85-2119

No.

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

BLOCK DRUG COMPANY, INC., et al.,

Petitioners,

vs.

MILTON HODOSH and RICHARDSON-VICKS, INC.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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QUESTIONS PRESENTED

1. Whether a U.S. Court of Appeals may defeat a grant of summary judgment by finding the existence of an issue of fact in the face of an unrebutted admission of record in the proceedings before a district court?

2. Whether a U.S. Court of Appeals may, in determining obviousness under 35 USC §103, and in accordance with Graham v. John Deere Co., 383 U.S. 1 (1966), fail to give full consideration to prior art which clearly discloses the feature claimed as patentable, by denigrating such prior art as "ancient"?

STATEMENT PURSUANT TO SUPREME COURT RULES 21 AND 28.1

The parties in the proceeding before the U.S. Court of Appeals for the Federal Circuit were as follows:

Appellants

1. Milton Hodosh
2. Richardson-Vicks, Inc. (now owned by Procter & Gamble, Inc.)

Appellees

1. Block Drug Company, Inc.
2. Block Drug Corporation
3. Dentco, Inc.

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No. _____

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1985

BLOCK DRUG COMPANY, INC., ET AL.,

Petitioners,

-v-

MILTON HODOSH
and
RICHARDSON-VICKS, INC.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

OPINIONS BELOW

The opinion of the District Court, granting petitioners' motion for summary judgment that the U.S. Patent

No. 3,863,006 is invalid, is set forth in Appendix A, and has been reported at ____ F. Supp. ____, 226 USPQ 645 (D.N.J. 1985).

The opinion of the U.S. Court of Appeals for the Federal Circuit, reversing the District Court's grant of summary judgment and remanding the case for trial, is set forth in Appendix B, and is reported at 786 F.2d 1136 (Fed. Cir. 1986).

JURISDICTION

The judgment of the U.S. Court of Appeals for the Federal Circuit sought be to reviewed herein was entered on March 24, 1986.

The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

CONSITUTIONAL PROVISIONS AND STATUTES INVOLVED

The constitutional provision involved here is Article I, §8, clause 8 of the Constitution of the United States.

The federal statutory provision involved herein is 35 U.S.C. §103.

Rule 56(e), Fed. R. Civ. P., is also involved herein.

STATEMENT OF THE CASE

This case arises from a patent infringement suit filed by respondents Hodosh and Richardson-Vicks, Inc. (collectively "Hodosh") against petitioners Block Drug Co. et al. ("Block").

The Patent in Suit

The patent involved is U.S. Patent No. 3,863,006 (the Hodosh patent), reproduced in Appendix C, which describes and claims a method of desensitizing teeth by the application of potassium nitrate (KNO_3). In the method of the patent, an aqueous solution of KNO_3 is applied to the teeth, or the teeth are brushed with a toothpaste containing KNO_3.

According to the Hodosh patent, the potassium nitrate treatment of the alleged invention is simple:

> In utilizing potassium nitrate as a desensitizing agent, it is simply necessary to dissolve potassium nitrate crystals in a liquid solution, preferably water; and then the solution so formed is liberally applied to the hypersensitive area by means of cotton or the like. [Col. 2, lines 7-11].

Potassium nitrate is an old and well-known chemical compound. It is also known as niter and saltpeter.

The Prior Art

The idea of putting a tooth desensitizing agent into toothpaste form is old. For example, Petitioner Block's SENSODYNE toothpaste is such a toothpaste. The prior art Rosenthal patent thereon, U.S. Patent No. 3,122,483, reproduced in Appendix D, describes and claims such a toothpaste.

The toothpaste example in the prior art Rosenthal patent has precisely the same formulation, i.e. the same ingredients and the same percentages as those in the Hodosh patent. The only difference is the use of potassium nitrate in place of strontium chloride:

Hodosh Patent Toothpaste Sample

Ingredient	Weight %
Potassium Nitrate	10.0
Water	36.2
Glycerin	25.0
Hydroxyethylcellulose	1.6
Polyoxyethylene sorbitan monolaurate	2.0
Micronized silica	24.0
Spearmint Oil	1.0
Saccharin	0.2

Rosenthal Patent Toothpaste Example 1

Ingredient	Weight %
Strontium Chloride $6H_2O$	10.0
Water	36.2
Glycerin	25.0
Hydroxyethylcellulose	1.6
Polyoxyethylene sorbitan monolaurate	2.0
Micronized silica	24.0
Spearmint Oil	1.0
Saccharin	0.2

In addition to Block's Rosenthal patent and Block's SENSODYNE toothpaste,

the district court considered several prior art publications which disclose the use of potassium nitrate to treat tooth pain. These publications are not "ancient" Chinese references, as the Federal Circuit characterized them. Rather, they are works in the Chinese language and were published in 1965 and 1963: (1) Ben Cao Gang Mu, which discusses the properties of "xiao shi" (potassium nitrate) and its use for treatment for "ya tong" (tooth pain); and (2) The Grand Dictionary of Chinese Medicine and Drugs, which cites Ben Cao Gang Mu and which, in the original Chinese text, also identifies "xiao shi" with the international chemical symbol for potassium nitrate, KNO_3.

Both Ben Cao Gang Mu and The Grand Dictionary of Chinese Medicine and Drugs are prior art publications under the patent statute. Both were provided to the district court with certified English translations. The translations were made by Mr. Roger Wei Ming Cao (Tsao), who is fluent in English and Chinese and is trained in chemistry and Chinese medicine. The accuracy of the translations was confirmed by Dr. Stephen H.Y. Wei, who is fluent in Chinese and English and is a professor of dentistry.

The District Court Decision

The district court's decision includes a comprehensive discussion of the prior art references involved and

sets forth a detailed analysis of "basic factual inquiries" delineated in Graham v. John Deere Co., 383 U.S. 1, 17 (1966).

With regard to the first Graham inquiry, the scope and content of the prior art, the district court noted that the prior art Rosenthal patent "undoubtedly includes" the method of treating hypersensitive teeth with a dentifrice containing strontium chloride, and that "the Hodosh patent merely substitutes potassium nitrate for strontium chloride." [48a] [Footnote omitted]. As to the issue of whether the prior art showed potassium nitrate to be an effective desensitizer of teeth, the court expressly stated:

> The Grand Dictionary of Chinese Medicine and Drugs, as of 1963,

> clearly revealed that KNO_3, which is undisputed to be the chemical formula for potassium nitrate, cures ya tong which undoubtedly translates to tooth pain and was apparently understood by plaintiff Hodosh to include tooth hypersensitivity itself. [50a] [Emphasis in original.]

Thus, the district court concluded that "as of at least 1963, prior art revealed potassium nitrate to be an antidote for tooth hypersensitivity." [50a]

Turning to the second Graham inquiry, the differences between the prior art and the claims at issue, the court stated as follows:

> The similarity of function between the Hodosh and Rosenthal patents cannot here be disputed. Nor is there any question but that all plaintiff Hodosh has done is to substitute potassium nitrate for strontium chloride, in an effort to reach a better result, both in terms of

> desensitizing teeth and in terms of doing so more safely than done previously. Factually, there is thus no dispute as to the difference between the claim at issue and the prior art. It only remains to decide whether such difference is significant, a decision which must be predicated upon whether one skilled in the art would have regarded plaintiff's use of potassium nitrate in his claim as obvious in light of the prior art references here disclosed. [55a-56a]

On the issue of the level of ordinary skill in the pertinent art, the district court accepted the level described by Hodosh as that attained by "an experienced researcher in the dental fields having academic training and field experience in dentistry, pharmacology, oral pathology and chemistry." [57a-58a]

The court concluded that one of ordinary skill in the art would have

found the Hodosh invention to have been obvious over the Rosenthal patent and the prior art. The district court regarded

> the prior art as not only well within the scope of the chemical and dental arts implicated by the Hodosh patent, but also as addressing itself to the precise issue discussed by such patent: does potassium nitrate alleviate tooth hypersensitivity? [51a] [Footnote omitted.]

The court rejected Hodosh's argument that one of ordinary skill would not have found the Chinese prior art references to be credible. As to Hodosh's assertion that others in the field regarded the Hodosh invention as novel and nonobvious, the court correctly referred to the statute, 35 U.S.C. §103, which requires an assessment of obviousness by one of ordinary

skill in the art in light of all knowledge conveyed by the prior art, not on the basis of the actual knowledge of any particular individual.

The district court recognized that "[o]bjective evidence ('secondary considerations') such as commercial success due to the merits of the invention, must when presented be considered as part of the obviousness equation." [68a-69a]

The court considered Hodosh's evidence of an alleged "long-felt need for a more effective, safer dentifrice for sensitive teeth," but nevertheless concluded that the Hodosh patent was invalid for obviousness under 35 U.S.C. §103.

The Federal Circuit's Decision

The Federal Circuit reversed the district court's grant of summary judgment, holding that questions of material fact remain with respect to the meaning of "ya tong" and "xiao shi" used in the Chinese references.

In its decision, the Federal Circuit relied heavily on the affidavits of Hodosh's experts, in particular, the affidavit of Dr. Shklar, which the Federal Circuit determined was "more than adequate to withstand the challenge of this summary judgment motion." [110a] While acknowledging Block's assertion that Hodosh's experts "either had no knowledge or training in the Chinese language or Chinese medicine or were unfamiliar with dentistry or

medicine generally," [97a] the Federal Circuit nevertheless entirely avoided discussing the competence of the Hodosh affiants.

Likewise, the Federal Circuit acknowledged Block's argument that the Chinese references correctly disclose many of potassium nitrate's characteristics, like burning with a violet flame, and the direct reference to the chemical symbol KNO_3 in the Grand Dictionary. [97a-98a] The Federal Circuit nevertheless determined that the affidavits presented by Hodosh raised a genuine issue of material fact which precluded summary judgment. In making its decision, the Federal Circuit adopted Hodosh's characterization of the Chinese references as "ancient".

Based on the Federal Circuit's view of the "ancient" prior art, and its determination that issues of fact remained as to the meaning of "xiao shi" and "ya tong" in light of the affidavits from Hodosh's "experts", the decision of the district court was reversed.

REASONS FOR GRANTING THE WRIT

I. Certiorari should be granted to determine whether the U.S. Court of Appeals for the Federal Circuit improperly vacated a grant of summary judgment by finding the existence of an issue of fact in the face of an unrebutted admission made of record in the proceedings before the district court.

The Federal Circuit, in deciding that a genuine issue of fact was created by the meaning of "ya tong", admonished the district court for improperly drawing an inference against Hodosh, the non-moving party, concerning the following statement made by Dr. Hodosh's German Patent agent to the German Patent Office:

> The supersensitivity of dentine has been known for a long time and can be traced back 4,000 years to the Chinese where it was known as "Ya Tong". [108a]

According to the Federal Circuit, the district court's characterization of this statement as a "binding admission" constituted "the resolution of a head-on factual controversy." [107a]

The Federal Circuit was apparently convinced by the testimony of Hodosh's expert, Dr. Shklar, that this statement was factually incorrect:

> The substance of Dr. Shklar's affidavit on behalf of Hodosh goes far beyond merely denying that ya tong means tooth hypersensitivity and thus is more than adequate to show an evidentiary conflict on the record with respect to this crucial point, thus precluding summary judgment. [109a]

The Federal Circuit ignored that Dr. Shklar, a dentist with no knowledge of Chinese, Chinese medicine or dentistry, is simply not competent to

testify as to the meaning of "ya tong." The district court, on the other hand, correctly recognized that Dr. Shklar's statements regarding translations were worthless:

> [T]he court . . . is required to regard as irrelevant certain of Professor Shklar's observations upon which plaintiffs rely quite heavily. Thus, for example, Shklar's attacks upon the translation leading up to the prior art reference embodied in The Grand Dictionary of Chinese Medicine and Drugs, see Shklar Aff. ¶ 5(B), at 28-30, or upon Chinese medicine as a whole, id. at 26-27, are not here regarded as particularly pertinent, since they require skill beyond the scope of "the experienced researcher in dental fields . . . ." [58a-59a]

Similarly, the affidavit on the meaning of "ya tong" provided by Hodosh's other expert, Mr. Yen, who has no training in dentistry or medicine, raises no genuine issue of material fact.

Absent these averments by incompetent affiants, Hodosh's arguments amount to nothing more than mere denials by counsel, which are insufficient to create a genuine issue of fact to defeat a grant of summary judgment. Matsushita Electric Industrial Co. v. Zenith Radio Corp., 106 S. Ct. 1348, 1356 (1986).

As Rule 56(e), Fed. R. Civ. P., specifically states:

> When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of his pleading, but his response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If he does not so respond, summary judgment, if appropriate, shall be entered against him.

A disclaimer of the statement to the German Patent Office was first made

at oral argument by Hodosh's attorney on October 9, 1984 and in a post-hearing submission. Even though Block pointed out the statement in September 1984, no disclaimer or explanation of the statement by Hodosh himself has ever been made, although respondents were not reticent in submitting additional materials six months after oral argument. Thus, the statement stands unrebutted apart from mere arguments of counsel, which cannot take the place of evidence lacking in the record. Matsushita, 106 S. Ct. at 1356.

In its opinion, the Federal Circuit stated its belief that:

> The fact issues herein must be resolved by trial in which the conflicting views of the experts will be subject to the refining fire of cross examination, a more effective means of arriving

> at the legal conclusion of obviousness vel non than perusal of ex parte affidavits and declarations of partisan experts lobbed at each other from opposing trenches. [111a-112a]

The Federal Circuit did not explain how statements of Hodosh's unqualified experts could be made to rise to the level of creating a genuine issue of material fact. Further, Hodosh's opportunity for presenting additional evidence on this point passed with its failure to come forward with any evidence from competent sources in response to Block's summary judgment motion, when it had ample opportunity to do so.

Hodosh's statement to the German Patent Office was not made gratuitously. Rather, the statement was a statement of fact, made with the express purpose of

seeking allowance of the German patent application. Now, in a different context, where the facts asserted in the statement are harmful to its position, Hodosh seeks to take an entirely contradictory position and deny the truth of the statement.

As the district court correctly noted, citing 2 Chisum, Patents, §5.03[3], at 5-100.11 - 5-104 (1984), such statements made with respect to prior art during prosecution cannot be later withdrawn. At stated in Chisum:

> It is now settled that an applicant's admission as to the relevant prior art - both in terms of available sources and in terms of the scope of the art - will be accepted as binding upon him. [Emphasis added; footnotes omitted.]

The Court of Customs and Patent Appeals, a predecessor of the Federal

Circuit,[1] in In re LoPresti, 333 F.2d 932 (CCPA 1964), stated:

> [Affidavits] cannot affect the admissions of appellants that the disclosures in the reference . . . is prior art and the case must be decided on the assumption it is prior art notwithstanding the affidavits.

333 F.2d at 934. See also In re Nomiya, 509 F.2d 566 (CCPA 1975) and In re Fout, 675 F.2d 297 (CCPA 1982). Thus, the district court was correct in holding that Hodosh's statement was "binding" and conclusive in the absence of evidence in the record to the contrary.

The Federal Circuit's opinion clearly connotes disagreement with the

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[1] The decisions of the U.S. Court of Customs and Patent Appeals and the U.S. Court of Claims have been adopted as precedent for the U.S. Court of Appeals for the Federal Circuit. South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982)

district court's decision that the Hodosh patent is invalid. See, e.g., n.5 of the Federal Circuit's opinion [115a], which cites a plethora of cases holding patents valid. Remarkably, the Federal Circuit went so far as to state that: "He [Hodosh] made the invention even if it should later be decided that it was known to the Chinese." [113a]

That the Federal Circuit simply disagrees with the outcome of a case does not provide basis for reversal of summary judgment under Rule 56, Fed. R. Civ. P. Cf. Dennison Manufacturing Co. v. Panduit Corp., 106 S. Ct. 1578 (1986) (Federal Circuit decision vacated and remanded in view of lack of adequate explanation by Federal Circuit of basis for judgment, specifically its failure to apply Rule 52(a), Fed. R. Civ. P.).

In summary, by substituting its judgment for that of the district court's, the Federal Circuit converted the district court's proper reliance upon Hodosh's unrebutted factual admission into an inference, improperly drawn against the non-moving party.

II. Certiorari should be granted to determine whether the U.S. Court of Appeals for the Federal Circuit improperly failed to give full consideration to prior art in determining obviousness under 35 U.S.C. §103 by discounting such prior art as "ancient".

The two most relevant prior art references relied upon by the district court, Ben Cao Gang Mu, and The Grand Dictionary of Chinese Medicine and Drugs, were written in the Chinese language and were published in 1965 and

1963, respectively. Together, they disclose "xiao shi" (potassium nitrate) and its use for the treatment of "ya tong" (tooth pain). In its opinion, the Federal Circuit adopts Hodosh's denigrating characterization of this art as "ancient Chinese prior art." Though based on Chinese knowledge assembled approximately 500 years ago, the references themselves are not "ancient."

As the district court recognized, citing Sakraida v. Ag Pro, Inc., 425 U.S. 273, 275 n.1 (1976), nothing in 35 U.S.C. §103 provides that older references should be given less credence or be entitled to less weight:

> Thus, for example, not withstanding that the labors of Hercules do not generally represent viable prior art, and that Greek mythology, in general, is not the best source of

> scientific data, nonetheless, the Supreme Court found Hercules' fifth labor to be among the prior art rendering obvious a patent on a water flush system to remove cow manure from the floor of a dairy barn. [64a]

The Federal Circuit has previously refused to follow the tenets of the Supreme Court's decision in Sakraida. See, e.g., Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1536, 1566 (Fed. Cir. 1983).

In discounting the Chinese prior art as "ancient", the Federal Circuit is also taking a position contrary to that of one of its predecessor courts. The Court of Claims,[2] in Caldwell v. United States, 481 F.2d 898, 903-04 (Ct. Cl. 1973), recognized that Thomas A.

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[2] See supra n.1.

Edison's demonstration of the principle of thermionic emission in 1884 was relevant prior art to the invention there in suit.

This case thus represents a departure not only from Supreme Court precedent, but from the Federal Circuit's own precedent.

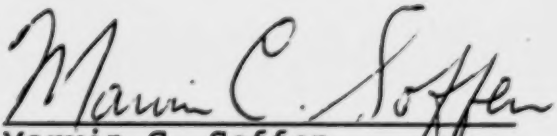
There is simply no justification for permitting Hodosh to enforce a patent monopoly on an idea that was known and disclosed in the prior art. To do so would encourage individuals to pore through similar references, seeking to patent "ancient" ideas, perhaps even incredible ideas (such as acupuncture was thought to be at one time), in the hope that they may ultimately prove to be commercially marketable. Under the

Federal Circuit's reasoning, old prior art from which such "inventions" are derived could not be used to establish obviousness under 35 U.S.C. §103. Such a decision cannot stand.

CONCLUSION

For the foregoing reasons, this Petition for a Writ of Certiorari should be granted.

Respectfully submitted,



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APPENDIX

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MILTON HODOSH and RICHARDSON-VICKS, INC.,	:	Civil Action No. 83-1110
Plaintiffs,	:	OPINION
-v-	:	
BLOCK DRUG COMPANY, INC., BLOCK DRUG CORP., and DENTCO, INC.,	:	
Defendants	:	

SAROKIN, District Judge.

Plaintiff Milton Hodosh ("Hodosh") brings this action alleging infringement of United States Patent No. 3,863,006 by defendants Block Drug Company, Inc., Block Drug Corp. and Dentco, Inc. Plaintiff Richardson-Vicks, Inc. ("R-V"), which possesses an

exclusive license for said patent, has been involuntarily joined as a party to this action, and also claims patent infringement by defendants. The matter is now before the court on defendants' motions for summary judgment on the basis of patent invalidity and patent misuse.

FACTS

On January 28, 1975, plaintiff Hodosh was awarded U.S. Patent No. 3,863,006 ("the Hodosh Patent"). As ultimately approved, the patent was comprised of six claims. They are:

> (1) The method of desensitizing hypersensitive dentin and cementum by applying thereto an agent the essential ingredient of which is a nitrate of one of the following alkali metals: potassium, lithium or sodium

said nitrate comprising between 1 percent and 20 percent by weight of said agent.

(2) The method of claim 1 further characterized in that said nitrate is potassium nitrate in an aqueous solution.

(3) The method of claim 2 further characterized in that said potassium nitrate comprises approximately 5 percent (5%) by weight and saturation of said aqueous solution.

(4) The method of claim 1 further characterized in that said nitrate is potassium nitrate mixed with a nontoxic paste.

(5) The method of claim 4 further characterized in that said nitrate comprises approximately ten percent (10%) by weight of said paste.

(6) The method of desensitizing hypersensitive dentin and cementum by applying thereto an aqueous solution, the essential ingredient of which is potassium nitrate

> said potassium nitrate comprising between 1% by weight and saturation of said aqueous solution.

Aff. of Marvin C. Soffen (7/9/84), Exh. 1; Memorandum in Support of Defendant's Motion for Summary Judgment of Patent Invalidity, Exh. A. The patent was awarded for plaintiff Hodosh's invention which, the patent states, "relates to a compound and treatment for eliminating or, at the very least, greatly reducing, discomfort and pain caused by tooth hypersensitivity or exposed cementum and/or dentin." Ibid. The invention was originally announced in the April, 1974 issue of the Journal of the American Dental Association ("JADA"), wherein Hodosh wrote:

> Tooth hypersensitivity affects a greater number of people than has been

previously suspected. Persons with this condition react painfully to heated or chilled foods, citric acid or sweets, or other everyday chemical, thermal, or tactile stimuli including toothbrush contact.

He continued:

The search has continued for a desensitizer that is easily and economically produced, that is effective in achieving the desired desensitizing function without irritation of the gingiva and discoloration of the teeth, that is not potentially toxic to the user if accidentally ingested, and that has a prolonged effect. These objectives seem to have been achieved with use of a new desensitizer.

* * *

The desensitizer, potassium nitrate, exhibits unusually effective, prolonged desensitizing action when it is applied to hypersensitive teeth (exposed dentin or cementum).

Appendix 1 to Plaintiff's Opposition to Defendants' Motion for Summary Judgment as to Patent Misuse ("Plaintiff's Appendix") at pp. 831-32. Based upon this discovery, Hodosh filed his initial application with the United States Patent Office on January 29, 1973. Such application, which included eleven claims, differed from the patent ultimately allowed in one major respect: whereas all of the approved claims were for the method of use of various compounds, nine of the eleven claims initially made were for the compounds themselves. The application was denied, on September 17, 1973. Aff. of William S. Feiler (7/3/84), Exh. 9, Paper No. 2.

On January 21, 1974, plaintiff Hodosh refiled his patent application

with the Patent Office. All eight claims regarding "the desensitizing agent" itself were cancelled, but plaintiff resubmitted those regarding method of use (Claims 9-11) for reconsideration and added four other "method" claims. See Id., Paper No. 4. In support of this application, Hodosh submitted his own affidavit, with exhibits detailing his credentials and publications, as well as the affidavits of eight patients who had been treated with the "invention." The Patent Office apparently remained unconvinced, and on March 8, 1974, rejected the claims for "lack of utility." Id., Paper No. 7, at 2. Hodosh then met with the Patent Office Examiner and, on, July 3, 1974, amended claims 9 and 15 to specify the

percentages of nitrate involved in such use. He also submitted his JADA article, and the declaration of forty-seven successfully treated patients. Id., Paper No. 7.

As a result, on January 28, 1975, Hodosh's patent was approved. In the interim, Hodosh had begun negotiations with R-V, see Defendant's Appendix 2,[1] and by agreement entered into in August, 1975, Hodosh grated R-V "an exclusive, worldwide license under the LICENSED PATENTS for [R-V] to make, use and sell the PRODUCT for the USE." Soffen Aff., Exh. 4 at 4. In return, Hodosh was to receive significant royalties.

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[1] Richardson-Vicks was then known as Richardson-Merrill, Inc.

R-V proceeded to test a dentifrice containing the patented use of potassium nitrate, known as Denquel, instituting the required procedures for review by the Food and Drug Administration ("FDA"). See Plaintiff's App. 4, 6. In July 1978, the FDA found that

> 5 percent potassium nitrate is safe but . . . there are insufficient data available to permit final classification of its effectiveness for [over the counter] use as a tooth desensitizer for the relief of oral discomfort.

47 Fed. Reg. 22754 (May 25, 1982), cited in R-V's Brief at 7-8. See Plaintiff App. 27. Pending a determination as to efficacy, the FDA allowed Denquel to be marketed, accompanied by a warning against continued use. See 47 Fed. Reg. 22749 (re labeling). As a result, R-V

began marketing Denquel in 1980. See Decl. of Nicholas O. Matt ¶ 4. As of October 13, 1981, the FDA still had not determined whether Denquel was effective, though it determined to take no action to remove the product from the market. Plaintiff's App. 3. Elsewhere, the product was greeted with considerably more enthusiasm. Denquel was provisionally accepted as a therapeutic agent by the American Dental Association (ADA") in July, 1979, Plaintiff's App. 9, and granted full acceptance and the ADA Seal of Approval on February 12, 1981. Plaintiff's App. 20. See Plaintiff's App. 26. In 1982, R-V began to market Denquel nationally.

In so doing, R-V entered into a market previously dominated by Block

Drug which had, since 1961, marketed a product known as Sensodyne toothpaste. According to R-V, "Sensodyne enjoyed a virtual monopoly of the desensitizing toothpaste market (approximately 85 to 90%);" its active ingredient is strontium chloride, which use is protected by U.S. Patent No. 3,122,483, dated February 25, 1964. R V's Brief at 14. See also Soffen Aff., Exh. 1 (Hodosh Patent, discussing Patent No. 3,122,483). Block Drug was aware of Hodosh's invention, and apparently considered, but rejected, developing a toothpaste for sensitive teeth utilizing potassium nitrate. Plaintiff's App. 59 at 137, 142-43. R-V claims that upon realizing the potential commercial threat posed by Denquel, Block Drug

initiated regulatory proceedings designed to delay or prevent R-V's marketing of such product, see Plaintiff's App. 11, 15-19, 34, 36-37, stepped up promotion of its own product, see, e.g., Plaintiff's App. 33, 36, 45, and ultimately developed its own potassium nitrate-based toothpaste, which was named Promise Toothpaste. See Plaintiff's App. 30, 32-43, 48. Later, fluoride was added to these products, which became known as Promise with fluoride and Sensodyne-F. See Plaintiff's App. 43, 45, 47, 49-53. However, the products have themselves encountered regulatory obstacles, in that the FDA contends that they are new drugs and thus subject to FDA approval prior to marketing. Indeed, the government has

initiated forfeiture proceedings, including one in this district, which is currently stayed, see United States v. Articles of Drug . . . consisting of Promise Toothpaste for Sensitive Teeth, Civil Action No. 83-3302, bench op. (October 28, 1983), on reconsideration, unpub. op. (January , 1983), as a result of Block Drug's failure to obtain such approval. Such issue is currently in litigation in the United States District Court for the Northern District of Illinois. See Plaintiff's App. 55-56.

Block Drug has also sought to purchase a license for the use of the Hodosh patent from R-V. In 1979, and again in 1981, these requests were denied, R-V having "concluded that we

will retain the exclusivity that we obtained from Dr. Hodosh under his patent and accordingly we will not sublicense Block Drug." Soffen Aff., Exh. 7. See also Id., Exh. 6. Nonetheless, R-V gives an implied license to "[e]ach purchaser of DENQUEL Sensitive Teeth Toothpaste . . .." Id., Exh. 5. Finally, in 1982, plaintiffs filed a request with the Patent Office for re-examination of Patent No. 3,863,006. Based upon plaintiffs' submission of certain prior art, see Feiler Aff., Exh. 10, Paper No. 1, the Examiner granted the request for reconsideration and held that such prior art raised substantial new questions of patentability. Feiler Aff., Exh. 10, Paper No. 8. However, consideration of a lengthy statement

submitted by Hodosh, Feiler Aff., Exh. 10, Paper No. 9, apparently satisfied the Examiner of the validity of the patent and a Certificate of Re-examination was issued on June 21, 1983. See Hodosh's Brief, Exh. A.

On March 30, 1983, plaintiff Hodosh filed the instant action alleging that Block Drug is infringing the Hodosh patent. On October 11, 1983, R-V involuntarily filed a complaint setting forth the same allegations. Defendants have answered, pleading counterclaims based on alleged antitrust violations. Extensive, and highly confidential discovery has occurred, and defendants now move for summary judgment on grounds of both patent invalidity and patent misuse.

DISCUSSION

Defendants first contend that the Hodosh patent is invalid for lack of novelty, under 35 U.S.C. § 102(b), and obviousness. 35 U.S.C. § 103. In support of such motion, they point to eight examples of prior art which, they argue, demonstrate that the method of desensitizing teeth by application of some form of potassium nitrate thereto, was both "described in a printed publication . . . more than one year prior to the date of the application for a patent," 35 U.S.C. § 102(b), and "obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103. Such examples are, essentially, of two sorts--the Chinese prior

art and the European prior art. The two are discussed below, seriatim.

A. The Chinese Prior Art

The Chinese prior art is contained in two references. See Feiler Aff., Exhs. 1-2; Aff. of Stephen H.Y. Wei (8/31/84), Exhs. 2-3. The first is a discussion of "xiao-shi" found in the "well recognized and respected treatise on Chinese medicine" Ben Cao Gang Mu, by Li Shi Zheng. Sei Aff. ¶ 9. There xiao shi is translated as "niter", and said to cure

> summer infections and the catching of colds, acute enteritis with severe vomiting, exertion thru excessive sexual activity and black jaundice, chronic abdominal pains, conjunctivitis, headache and tooth pain. (Ya-Tong or Ya Teng).

Feiler Aff., Exh. 1, at 8. "Painful swelling of the gums" is among the other ailments which xiao shi is claimed to address in Ben Cao Gang Mu, published in 1930, 1954 and 1965.

The second Chinese source, published in 1963, is in accord. Hence, The Grand Dictionary of Chinese Medicine and Drugs states that xiao shi is one name linked to niter, and to its chemical formula, KNO_3, which is the symbol for potassium nitrate. The Grand Dictionary quotes the same Ming dynasty source as labeling KNO_3 a cure for, inter alia, tooth pain. Feiler Aff., Exh. 2 at 3. Both such sources were translated by Roger Wei-Ming Tsao (Cao), who is trained as a doctor in Chinese medicine and is a bilingual tutor. See

Aff. of Roger Wei-Ming Tsao (9/6/84) ¶¶ 5-9. This translation is concurred in by Dr. Stephen H.Y. Wei, a professor of dentistry fluent in Chinese. Dr. Wei confirms that "xiao shi is a Chinese name for potassium nitrate" and adds that "ya tong means tooth pain, or pain associated with the dental structure including hypersensitivity of tooth surfaces." Wei Aff. ¶ 9.

Plaintiffs have challenged these sources, upon which defendants relied most heavily at oral argument, see Transcript of Proceedings (10/9/84) at 45-52, on several grounds. First, they argue that, on a formal level, the dates of the Chinese references are not clear, and the extent to which they are direct reprints of original sources,

rather than information supplied by subsequent editors, undelineated. More significantly, relying on the Affidavit of Dr. Gerald Shklar, Charles A. Brackett Professor of Oral Pathology at the Harvard School of Dental Medicine, and an acclaimed expert in dentistry, see generally Aff. of Gerald Shklar (8/24/84) ¶ 1 and Exh. 1, plaintiffs argue that xiao shi is not accurately translated as "niter", or as potassium nitrate, id. ¶ 5(b), at 28-37, and that ya tong "is an aching or throbbing resulting from decay, and pulp infection [and] not a term to be used to describe the pain associated with tooth sensitivity." Id. at 37 n.19. Plaintiffs also attempt generally to discredit the Ancient Chinese texts upon which defendants rely. Id. at 26-27.

Specifically, plaintiffs point to "obvious inaccuracies in the translations" utilized by defendants, concluding that xiao shi should never have been translated as "niter", but rather, should have been translated, literally, as "consumer of stones," id. at 29-30, or chemically, as sodium carbonate or a sodium carbonate-bicarbonate mixture. Id. at 30, 36-37. The incomprehensible or inconsistent nature of the inflated claims made on behalf of xiao shi are documented, leading Dr. Shklar ultimately to conclude that "the same name was applied to different materials and the same material was given different names . . .. The problem arose . . . when the compiler and/or translator tried to assign one name to all of these

materials, and then concluded, on the basis of a false premise, that the one name represents one material." Id. at 35 (emphasis in original). He thus states that "neither I, nor, in my opinion, any one skilled in the dental research arts, could have a clear understanding of what was being described in these [Chinese references]." Plaintiffs bolster this position by noting that potassium nitrate simply cannot do all that the Chinese claimed it could. See Aff. of Abraham Sunshine ¶ 2. They also dispute defendants' translation qua translation, arguing that xiao shi may indicate many different materials. See Aff. of Gordon K.D. Yen (10/1/84) ¶¶ 3-6, 8(a)-(d). Plaintiffs' translator also takes issue with defendants'

contention that ya tong refers in any way to sensitive teeth. Id. ¶¶ 7, 8(e).

Defendants, however, argue that "Dr. Shklar's opinions are based upon an apparent lack of understanding of the Chinese language and reflects [sic] a certain hostility to Chinese Medicine," Wei Aff. ¶ 11, and that plaintiffs' translator "has no technical training or experience in Chemistry or Chinese medicine." Defendants' Letter Memorandum (10/9/84) ¶ 1. They also point out that Ben Cao Gang Mu describes a substance that burns as does potassium nitrate, i.e., "with a purplish-blue smoke," Wei Aff. ¶ 11, that dissolves in water as does potassium nitrate, see Feiler Aff., Exh. 12 at 695, and that can be used as gun powder. Feiler Aff., Exh. 9 at

1248, Exh. 12 at 697; Wei Aff. ¶ 11. Moreover, defendants note that even Hodosh himself has stated, before the German Patent Office, that "[t]he super-sensitivity of dentine has been known for a long time and can be traced back 4000 years to the Chinese where it as known as 'Ya Tong,'" Feiler Aff. Exh. 13, though plaintiff disclaimed such position at oral argument. Transcript of Proceedings at 57-58.[2] Finally, defendants label "speculation" the argument of plaintiffs' translator to the effect that xiao shi might be sodium sulfate and, indeed, argue that Ben Cao

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[2] It should, however, be noted that Exhibit 10 to the Affidavit of Professor Shklar translates ya tong consistently with tooth sensitivity, as a reaction to cold.

Gang Mu establishes the contrary proposition. See Feiler Aff., Exh. 1 at 8.

B. The European Prior Art

The European prior art is contained in six references, Feiler Aff., Exhs. 3-8, none of which were discussed by defendants at oral argument. Three of the references, in turn, rely upon a single statement of the French surgeon Guy de Chauliac to the effect that a mixture of "cuttlebone, small white sea shells, pumice, burnt stag's horn, nitre, alum, rock salt, burnt roots of iris, aristolochia, and reeds" could create an effective dentifrice. Feiler Aff., Exhs. 3-5 (emphasis added). Additionally, a 1963 treatise by the British Professor of Physics William

Salmon states that nitrum "held in the Mouth . . . immediately helps the Toothach, If burnt and used in a Dentifrice, it cleanses and whitens the Teeth." Id., Exh. 6 at 53. Similarly, a reference work by Hardianus a Mynsicht, translated into English in 1682, describes a mixture, including "nitre" as a "tincture for the toothach." Id., Exh. 7 at 55-56, 147, 172. Finally, Pliny the Elder, in his Historie of the World, The Second Tome, translated into English in 1601, describes the use of nitre to "easeth the toothach, if the mouth and gums be washed therwith," or if burned, as a dentifrice. Id., Exh. 8 at 422.

Plaintiffs are not persuaded by these references. They argue, first,

that defendants' translation of "nitre" as potassium nitrate is erroneous: "it is common knowledge that these terms means sodium carbonate and/or a sodium carbonate-sodium bicarbonate mixture . . .." See Shklar Aff. ¶ 5(A) and 15-16 and Exhs. 6-9. Second, they contend that defendants misinterpret the use of the term "toothach" in the European prior art, arguing that it refers "to pain in the teeth resulting primarily from infection, decay or injury to the tooth . . .," id. at 17, and not to any particular sensitivity, or to a process of desensitization. Plaintiffs argue that these references are all based upon ancient formulae, which "are recognized as nonsense by today's standards," id. at 21, and which derive from either "the

humors, spirits and alchemy of the Dark Ages," id. at 20, or had whatever medicinal effect they did by virtue of their use of wine, opium, or other narcotic substances. Id. at 21.

Defendants, however, insist that nitre was well known to the world to mean "naturally occurring potassium nitrate." Shklar Aff., Exhs. 7, 9; Feiler Aff., Exh. 9. Nonetheless, defendants did not press the significance of the European prior art at oral argument.

C. Lack of Novelty - "Anticipation"

Defendants' first claim is that in light of all the above, the Hodosh patent is invalid for lack of novelty, in that it was "anticipated" by the

prior Chinese and European art. This claim is governed by 35 U.S.C. § 102(b), which states:

> A person shall be entitled to a patent unless -
>
> * * *
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

This provision of the patent laws is "designed to prevent withdrawal by an inventor, as the subject matter of a patent, of that which has already in the possession of the public." In re Wyer, 665 F.2d 221, 226 (C.C.P.A. 1381), citing In re Bayer, 568 F.2d 1357, 1359 (CCPA 1978). See also Tyler Refrigeration Corp. v. Kysor Industrial Corp.,

553 F. Supp. 279, 282 (D. Del. 1982). It requires that the pertinent publication be "available to that class of persons concerned with the art to which the document relates and thus most likely to avail themselves of its contents." Boileau v. Diamond, 659 F.2d 247, 248 (D.C. Cir. 1981), quoting Garrett Corp. v. United States, 422 F.2d 874, 878 (Ct. Cl.), cert. denied, 400 U.S. 951 (1970). Availability is often a question of fact, based upon an evaluation of factors such as classification and indexing. In re Wyer, supra, 655 F.2d at 226. Thus, in order to prevail on a section 102(b) claim, one in the position of defendants herein must show that

> [the pertinent] document has been disseminated or otherwise made available to the extent that persons inter-

> ested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it and recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation.

Id. at 226, quoting I.C.E. Corp. v. Armco Steel Corp., 250 F. Supp. 738, 743 (S.D.N.Y. 1966). In other words,

> section 102(b) requires a determination of whether one skilled in the art to which the invention pertains could take the description of the invention in the prior publication and combine it with his own knowledge of the particular art and from this combination be put in possession of the invention on which a patent is sought.

In re Sasse, 629 F.2d 675, 681 (C.C.P.A. 1980) (emphasis in original), quoting In re LeGrice, 301 F.2d 929, 944 (C.C.P.A. 1962). See also In re Donohue, 632 F.2d 123, 125-26 (C.C.P.A.

1980); Application of Samour, 571 F.2d 559, 562 (C.C.P.A. 1978); Titanium Metals Corp. v. Mossinghoff, 603 F. Supp. 87, 89-90 (D.D.C. 1984); Ralston Purina Co. v. Far-Mar-Co., Inc., 586 F. Supp. 1176, 1,221 (D. Kansas 1984) (citing cases); Preemption Devices Inc. v. Minnesota Mining and Manufacturing Co., 559 F. Supp. 1250, 1259 (E.D. Pa. 1983), aff'd, 732 F.2d 903 (Fed. Cir. 1984); Regents of the University of California v. Howmedica, Inc., 530 F. Supp. 846, 859 (D.N.J. 1981), aff'd,

676 F.2d 687 (3d Cir. 1982).[3] However, it is also true, as plaintiffs argue, that because "anticipation" is a technical defense to charges of patent infringement it is to be rigorously applied: "there is no anticipation unless all of the same elements are found in exactly the same situation and united in the same way . . . in a

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[3] There is some conflict in the Supreme Court authorities as to whether the appropriate standard is an "enablement" standard, pursuant to which a prior publication constitutes anticipation only if it enables one skilled in the art "to understand the nature and operation of the invention, and to carry it into practical use," Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 555 (1870), or whether a complete description suffices, although it does not "teach a manufacturer how to make the patented [product]." Cohn v. United States Corset, 93 U.S. 366, 377 (1876). See generally 1 Chisum, Patents § 3.04[1], at 3-198 - 3-23 (1981). However, the resolution of such conflict is unnecessary to the instant case.

single prior art reference." Perkin Elmer Corp. v. Computervision Corp., 732 F.2d 888, 894 (Fed. Cir.), cert. denied, 105 S. Ct. 187 (1984), cited in Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 619 (Fed. Cir. 1985) ("Anticipation is established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention."); Codex Corp. v. Milgo Electronic Corp., 71 F.2d 622, 628 (1st Cir. 1983); Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771 (Fed. Cir.), cert. denied, 104 S. Ct. 1284 (1984).

Citing this line of cases, plaintiffs argue that no single prior art reference raised by defendants describes

(a) desensitizing hypersensitive dentin and cementum;

(b) by applying thereto the essential ingredient potassium nitrate;

(c) in a mixture with nontoxic paste;

(d) in the amount of between 1 percent and 20 percent by weight of the nontoxic paste.

Hodosh Brief at 10-11. Defendants, however, claim primarily in Reply and at oral argument, that these elements are established with absolute identity by Block's Rosenthal Patent No. 3,112,483, Defendants' Brief, Exh. E, except that the former utilized strontium chloride in lieu of potassium nitrate, in the exact same proportions. See Defendants' Brief, Exh. J. It is but a small step, they contend, to substitute the latter, particularly in

light of the Chinese prior art references, and taken together, the patent and the publications therefore anticipate the Hodosh patent and render it invalid.

While the court finds this argument persuasive in the obviousness context, see infra at 28-34, it cannot be regarded as dispositive with respect to the "technical defense" of anticipation. This is so first because, as the cases note, section 102(b) requires that each and every element of a claim be present in a single prior art reference. Defendants' theory, however, is based upon at least two prior art references: The Grand Dictionary of Chinese Medicine and Drugs, Feiler Aff., Exh. 2; Wei Aff., Exh. 3, and the

Rosenthal patent, Defendants' Brief, Exh. E, as well as plaintiff Hodosh's concession regarding the translation of ya tong. See Defendant's Brief, Exh. J. As such, it cannot be said to be anticipated by the Chinese printed publication which, after all, alone stands only for the proposition that, KNO_3 alleviates tooth pain. See Studiengesellschaft Kohle v. Dart Industries, Inc., 726 F.2d 724, 726-27 (Fed. Cir. 1984) ("What [defendant] asked the trial court to do, and what it would have us do on appeal, is to combine the teachings of the references to build an anticipation. That would be contrary to settled law, and the trial court was correct in refusing to do so."). Nor, even applying more lib-

eral interpretations of section 102(b) which allow findings of anticipation where there are only minor differences between the prior art and the patent at issue, Reynolds Metals Co. v. Aluminum Co. of America, 609 F.2d 1218, 1220 (7th Cir. 1979), quoting Popeil Brothers, Inc. v. Schick Electric Co., 494 F.2d 162, 165 (7th Cir. 1975); see generally 1 Chisum, supra, § 3.02, at 3-6.1 and n.3.2, can the Chinese references be found to discuss a method of desensitizing hypersensitive teeth by applying a solution of potassium nitrate and nontoxic paste. For this reason alone, defendants' section 102(b) challenge to plaintiffs' patent must fail.

Appendix A

Moreover, although it appears to be the case that combining the information putatively derived from the Chinese references--that potassium nitrate is a remedy for sensitive teeth--with the knowledge that one skilled in the art ought to have had regarding the possibility of incorporating such remedy in a dentifrice--knowledge derived from the Rosenthal patent, for example--it is not clear to the court that such skilled person, "exercising reasonable diligence," would be able to locate the prior art references raised by defendants, given the esoteric nature of the references here cited. See supra at 33-34. The "availability" of the prior art reference is, in this sense, subject to some

doubt. For this reason too, then, defendants' motion for summary judgment on grounds of lack of novelty, or anticipation, must be denied.

D. Obviousness

Defendants' second claim is that plaintiffs' patent should be declared invalid on grounds of obviousness. This separate claim is governed by 35 U.S.C. § 103, which states:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall

not be negated by the manner in which the invention was made.

The "basic factual inquiries" underlying this section were delineated by the Supreme Court in Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966).

> Under § 103, the scope and content of the prior art to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt by unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

See also Sakraida v. Ag Pro, Inc., 425 U.S. 273, 279-80 (1976); Dann v. Johnston, 425 U.S. 219, 226 (1976); Anderson's - Black Rock, Inc. v. Salvage Co., Inc., 396 U.S. 57, 62 (1969).[4]

The resulting analysis differs from that employed in the novelty or anticipation context discussed above in several important respects. First, the obviousness inquiry does not require

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[4] The Graham Court also held that, in the obviousness context, "the ultimate question of patent validity is one of law, 383 U.S. at 17, citing A. & P. Tea Co. v. Supermarket Corp., 340 U.S. 147, 155 (1950), based upon a resolution of the factual issues identified herein. Upon resolution of such issues, resolving all doubts against the moving party, as below, summary judgment becomes appropriate. See, e.g., Union Carbide Corp. v. American Can Co., 724 F.2d 1567, 1571 (Fed. Cir. 1984), citing Chore-Time Equipment, Inc. v. Cumberland Corp., 713 F.2d 774, 778-79 (Fed. Cir. 1983).

that all elements of the patent at issue be revealed in a single prior art reference; rather, multiple references may be combined to determine "the scope and content of the prior art." See, e.g., EWP Corp. v. Reliance Universal Inc., 755 F.2d 898, 907 (Fed. Cir. 1985); Lear Siegler, Inc. v. Aeroquip Corp., 733 F.2d 881, 889 (Fed. Cir. 1984); Orthopedic Equipment Co., Inc. v. United States, 702 F.2d 1005, 1013, (Fed. Cir. 1983). This, of course, is crucial here, where such combination is precisely what defendants seek to show. Second, whereas the anticipation defense allows a patentee to argue that, exercising reasonable diligence, it could not locate the prior art cited, or recognize or comprehend therefrom

the essentials of the patent, obviousness doctrine assumes an hypothetical omniscient inventor, with "perfect knowledge of all the pertinent prior art - however obscure its source." 2 Chisum, supra, § 5.04[1], at 5-135 and n.4. See, e.g., Union Carbide Corp. v. American Can Co., 724 F.2d 1567, 1572 (Fed. Cir. 1984); Application of Wood, 599 F.2d 1032, 1036 (C.C.P.A. 1979); Systematic Tool & Machine Co. v. Walter Kidde & Co., Inc., 555 F.2d 342, 348 n.4 (3d Cir. 1977); Aluminum Co. of America v. Amerola Products Corp., 552 F.2d 1020, 1026 (3d Cir. 1977). For these reasons, the obviousness problem demands a "broader, more general" inquiry than does anticipation, see, e.g., Lam, Inc. v. Johns-Manville

Corp., 668 F.2d 462, 468 (10th Cir.), cert. denied, 456 U.S. 1007 (1982), which is "a strictly technical defense." See, e.g., Kamei-Autokomfort v. Eurasian Automotive Products, 553 F.2d 605, 607 (9th Cir.), cert. denied, 434 U.S. 860 (1977). Hence, the fact that the court has found defendant's section 102(b) argument to fail does not doom the section 103 argument to a similar fate. Indeed,

> a disclosure that anticipates under § 102 also renders the claim invalid under § 103, for "anticipation is the epitome of obviousness," In re Fracalossi, 681 F.2d 792 (C.C.P.A. 1982). The reverse is not true, for the need to determine obviousness presumes anticipation is lacking.

Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1548 (Fed. Cir. 1983). See

also Kwik-Site Corp. v. Clear View Manufacturing Co., Inc., 758 F.2d 167, 173 (6th Cir. 1985). See generally 2 Chisum, supra, § 5.01, at 5-4 - 5-4.1 ("Nonobviousness is distinct from novelty in the sense that an invention may be obvious even though it is not identically disclosed anywhere in the prior art.").

Expressed in terms of the Graham v. Deere inquiry, defendants' obviousness argument is as follows: the prior art is constituted by the Rosenthal patent plus the knowledge, derived from the European and, primarily, the Chinese references, that potassium nitrate alleviates tooth sensitivity; taken together, these facts render obvious to one skilled in the

field of dental research the subject matter of the Hodosh patent. Plaintiffs respond, as noted, by questioning the content of the prior art, arguing that such art nowhere describes "the use of the essential ingredient, potassium nitrate, as a desensitizing agent in a nontoxic paste in the amount of one percent to twenty percent, as claimed in the Hodosh . . . patent, and the absence of the use of this material in the prior art," Hodosh Brief at 13, citing Shklar Aff. § 6, at 37, and pointing to a level of skill attained by "an experienced researcher in the dental fields having academic training and field experience in dentistry, pharmacology, oral pathology and chemistry." Hodosh Brief at 13, citing

Shklar Aff. ¶ 4(D), at 11. In further submissions, plaintiffs also point to the secondary consideration "that, notwithstanding the availability of [the prior art references pointed to by defendants], the search for an effective and universally safe desensitizing material continued for the past 150 years." Plaintiffs' Letter Memorandum (10/2/84) at 1.

1. Prior Art

The prior art, as revealed by the Rosenthal patent, undoubtedly includes the method of treating hypersensitive teeth with a dentifrice, there a dentifrice containing 0.5 percent to 20 percent strontium chloride. See Defendants' Brief, Exh.

E. Without altering the proportions of other ingredients, the Hodosh patent merely substitutes potassium nitrate for strontium chloride.[5] Plaintiffs argue that such substitution was non-obvious. Defendants point to prior art which, they argue, stands for the proposition that potassium nitrate was known to be an effective desensitizer of teeth.

Plaintiffs' primary attack is upon the content of such prior art. They argue that it does not make clear that potassium nitrate combats tooth hypersensitivity. Based upon the

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[5] Whether such substitution can ever be grounds for patentability is more appropriately addressed infra, at 25-26, with respect to the putative differences between the patent at issue and the prior art.

undisputed evidence before the court, the court disagrees. The Grand Dictionary of Chinese Medicine and Drugs, as of 1963, clearly revealed that KNO_3, which is undisputed to be the chemical formula for potassium nitrate, cures ya tong which undoubtedly translates to tooth pain and was apparently understood by plaintiff Hodosh to include tooth supersensitivity itself. See Feiler Aff., Exh. 13.[6] Though currently disclaimed, the court finds such understanding based upon access to the very prior art raised by plaintiff, to be not only

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[6] This 1963 reference, which includes the chemical formula for potassium nitrate, renders irrelevant either the correct translation of xiao shi or the appropriate meaning to be attributed to "niter."

highly probative, but also a binding admission. See 2 Chisum, supra, § 5.03[3], at 5-100.11 - 5-104 (citing cases). Taken together, these references demonstrate that, as of at least 1963, prior art revealed potassium nitrate to be an antidote for tooth hypersensitivity. Hence, the court finds the undisputed facts to identify the prior art as not only well within the scope of the chemical and dental arts implicated by the Hodosh patent,[7] but also as addressing itself to the precise issue discussed by such patent: does potassium nitrate alleviate tooth hypersensitivity?

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[7] Such scope is not disputed.

2. Differences Between Prior Art and Claims at Issue

Plaintiffs' claim of difference between the prior art and the Hodosh patent is twofold. First, they argue that such difference stems from the use of potassium nitrate, "and the absence of the use of this material in the prior art." Plaintiffs' Brief at 13. Second, they contend that potassium nitrate's properties of high effectiveness in desensitizing teeth coupled with safety of use were "unexpected." Ibid.

Neither of thee arguments suffice to support patentability. First, to the extent that plaintiffs rest the patentability of their product on the mere substitution of one material for another, enhancing the result thereby

achieved, it is well settled that the resulting patent clair is barred by section 103. See, e.g., Sinclair Co. v. Interchemical Corp., 325 U.S. 327, 335 (1934) ("Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put into the last opening in a jig-saw puzzle. It is not invention.")' Brunswick Corp. v. Champion Spark Plug Co., 689 F.2d 740, 750 (7th Cir. 1982); Eltra Corp. v. Basic, Inc., 599 F.2d 745, 756-57 (6th Cir. 1979), cert. denied, 444 U.S. 942 (1980); Centsable Products Inc. v. Lemelson, 591 F.2d 400, 403 (7th Cir. 1979), cert. denied, 444 U.S. 840 (1980); AMP, Inc. v. Burndy Corp., 332 F.2d 236, 239 (3d Cir.), cert. denied,

379 U.S. 844 (1964). See also Graham v. John Deere Co., supra, 383 U.S. at 10 ("A change of material should not give title to a patent. As the making of a ploughshare of cast rather than of wrought iron; a comb of iron instead of horn or of ivory . . ."), quoting VI Writings of Thomas Jefferson, at 181 (Washington ed.) (Letter to Isaac McPherson); Hotchkiss v. Greenwood, 52 U.S. (11 How.) 248, 267 (1851). Of course, to the extent that such material is not "well known" or "expected" to perform in the substituted manner, such substitution may indeed be patentable. Engelhard Minerals & Chemicals Corp. v. Anglo-American Clays Corp., 586 F. Supp. 435, 446 (M.D. Ga. 1984) (citing cases). See also Brunswick

Corp. v. Champion Spark Plug, supra, 689 F.2d at 750-51, citing Tracor, Inc. v. Hewlett-Packard Co., 519 F.2d 1288 (7th Cir. 1975). See generally 2 Deller's Walker on Patents § 112, at 248 (1964). Similarly, while a patent may be based upon a combination of known elements, such combination is not patentable if it is not itself obvious, see, e.g., Lindemann Maschinenfabrik, supra, 730 F.2d at 1462; Union Carbide Corp. v. American Can Co., supra, 724 F.2d at 1575, or if, for example, it yields a "synergistic result," i.e., a new or different function. See, e.g., Sakraida, supra, 722 F.2d at 1548-49 (new or different result not required).

The similarity of function between the Hodosh and Rosenthal

patents cannot here be disputed. Nor is there any question but that all plaintiff Hodosh has done is to substitute potassium nitrate for strontium chloride, in an effort to reach a better result, both in terms of desensitizing teeth and in terms of doing so more safely than done previously. Factually, there is thus no dispute as to the difference between the claim at issue and the prior art. It only remains to decide whether such difference is significant, a decision which must be predicated upon whether one skilled in the art would have regarded plaintiff's use of potassium nitrate in his claim as obvious in light of the prior art references here disclosed.

3. Level of Ordinary Skill in the Pertinent Art

Because both the scope and content of the prior art and the differences between the prior art and the patent at issue are capable of resolution based upon the undisputed facts before the court, it only remains to address the third factual inquiry mandated by Graham v. John Deere before making an initial determination of obviousness, subject to secondary considerations. This third inquiry regards the level of ordinary skill in the pertinent art. Plaintiffs describe such level as that attained by "an experienced researcher in the dental fields having academic training and field experience in dentistry, pharmacology, oral pathology and

chemistry." Hodosh Brief at 13, citing Shklar Aff. ¶ 4(D), at 11. This description is uncontroverted by defendants and will be accepted by the court. Such acceptance, however, is of little consequence to the resolution of the instant dispute, as is, apparently, often the case. See generally 2 Chisum, supra, § 5.03[4], at 5-109 - 5-114. See, e.g., Chore-time Equipment, supra, 713 F.2d at 779. However, the court notes that, in accepting plaintiffs' characterization of the level of ordinary skill in the pertinent art, it is required to regard as irrelevant certain of Professor Shklar's observations upon which plaintiffs rely quite heavily. Thus, for example, Shklar's attacks upon the translation leading up

to the prior art reference embodied in The Grand Dictionary of Chinese Medicine and Drugs, see Shklar Aff. ¶ 5(B), at 28-30, or upon Chinese medicine as a whole, id. at 26-27, are not here regarded as particularly pertinent, since they require skill beyond the scope of "the experienced researcher in dental fields . . .." On the other hand, to the extent that Shklar's criticisms are based upon the facial incomprehensibility of and inconsistencies in the text itself, leading him to conclude "that neither I, nor, in my opinion, any one skilled in the dental research arts, could have a clear understanding of what was being described . . .," id. at 34, see id. at 31-34, such criticisms are certainly germane to the analysis herein.

Appendix A

4. Obviousness in Light of the Graham Factors

Notwithstanding these criticisms, the court finds the Hodosh patent to be invalid as obvious. At the very least, the teachings of the prior art should "have suggested (expressly or by implication) the possibility of achieving . . . improvement by combining such teachings along the line of the invention in suit," In re Sernaker, 702 F.2d 989, 994 (Fed. Cir. 1983) (emphasis added), that is, by substituting KNO_3 for the strontium chloride used in the otherwise identical Rosenthal patent. See also Vandenberg v. Dairy Equipment Cok., 740 F.2d 1560, 1566 (Fed Cir. 1984) (". . .

in order to combine the teachings of the prior art references, the prior art must suggest the desirability of the combination."), citing Lear Siegler, Inc. v. Aeroquip Corp., supra; Electro-Nucleonics, Inc. v. Mossinghoff, 592 F. Supp. 608, 611 (D.D.C. 1984) (". . . prior art references are evaluated not only for what they expressly teach, but also for what they would fairly suggest to one of ordinary skill in the art.") Such holding is strengthened by the European prior art which, while ambiguous because of the several conflicting definitions in the term "niter," at least suggest to one skilled in the art that potassium nitrate ought to be tried as a cure for tooth pain in general. See 2 Chisum, supra, § 5.04[1],

at 5-136.4 (". . . in certain situations, obviousness is properly predicated on an obvious to try concept. For example, a new problem may arise. The prior art suggests that the solution would ordinarily be obvious even though the hypothetical mechanic would have to try several of the permutations.") (citing cases).

Plaintiffs' attack on this holding is essentially threefold. First, they argue that the dental researcher of ordinary skill would not have found the references here cited to be credible and, as such, would not have found it obvious to substitute potassium nitrate for strontium chloride. The court rejects this argument. Plaintiffs' attack on both the

European and the Chinese prior art references based upon their allegedly unscientific nature has been implicitly rejected by the Supreme Court, which has taken judicial notice of even prior art gleaned from classic mythology. Sakraida, supra, 425 U.S. at 274 n.1 (Hercules' method for cleaning stables). See P. Rosenberg, Patent Law Fundamentals § 98.04, at 9-33 (1984). Nor, if it is true that KNO_3 alleviates tooth sensitivity, is such reference in the prior art rebutted by the existence of errors in the reference such as, for example, the claim that KNO_3 is a cure for "exertion through excessive sexual activity." Whatever the merits of the other aspects of the Chinese references, the fact that they reveal KNO_3

to be a cure for ya tong is what is dispositive here. The reference clearly discloses such function of potassium nitrate, albeit in the context of otherwise incredible, and even erroneous, descriptions of the compound's quality. Thus, for example, notwithstanding that the labors of Hercules may not generally represent viable prior art, and that Greek mythology, in general, is not the best source of scientific data, nonetheless, the Supreme Court found Hercules' Fifth Labor to be among the prior art rendering obvious a patent on a water flush system to remove cow manure from the floor of a dairy barn. Sakraida, supra, 425 U.S. at 274-75. Much more ought the specific instruction of a

1963 Chinese text to the effect that potassium nitrate, identified by its formal Western chemical formula, is a cure for what plaintiff has identified as tooth sensitivity, preclude subsequent efforts to obtain a patent monopoly on the use of such chemical for that purpose.

Second, plaintiffs attack the conclusion that the Hodosh patent is obvious by presenting evidence that others in the field, including the patentee of the Rosenthal patent, regarded Hodosh's invention as novel and nonobvious. See Hodosh's Brief, Exh. B at 27, 28, 166; Shklar Aff. ¶ 4(E), at 12. Such evidence is, of course irrelevant; the court here considers not the actual knowledge of any

particular individuals but, as discussed, supra at 21, the complete and absolute knowledge possessed by the hypothetical omniscient skilled artisan. The court concludes that such person would, based upon the Chinese prior art references, have substituted potassium nitrate for the strontium chloride utilized in the Rosenthal patent. That other, real persons, not possessed of this knowledge, would not have done so does not, and cannot, alter the court's conclusion. See, e.g., EWP Corp. v. Reliance, supra, 755 F.2d at 907 ("Patentability under the statute, § 103, is a decision made on the basis of a hypothesis: Would the invention have been obvious 'to a person having ordinary skill in the art

to which the subject matter pertains' in the light of all knowledge conveyed by 'prior art' as defined by statute and case law. It is a decision which must be made by courts because the law assigns that task to them. The function of witnesses, expert and otherwise, is to assist the court in determining and comprehending facts.").

Finally, plaintiffs argue that secondary considerations preclude a finding of obviousness, contending that the fact that notwithstanding the existence of the prior art references pointed to by defendants, "the search for an effective and universally safe desensitizing material continued for the past 150 years." This argument is addressed below.

5. Obviousness in the Light of Secondary Considerations

In Graham, the Supreme Court stated that secondary considerations "may have relevancy" as indicia of obviousness or nonobviousness. However, since Graham, courts have made clear that such considerations must be recognized and addressed by trial courts. See, e.g., Kwik-Site Corp. v. Clear View, supra, 758 F.2d at 173 (citing cases); Fromson v. Advance Offset Plate, Inc., 755 F.2d 1549, 1557 (Fed. Cir. 1985) ("Objective evidence ('secondary considerations') such as commercial success due to the merits of the invention, must when presented be considered as part of the obviousness

equation. The district court erred here in reaching a conclusion on obviousness before considering the evidence of secondary considerations, and in then evaluating the latter solely on its 'gap filling' capacity."); In re Vamco Machine and Tool, Inc., 752 F.2d 1564, 1573 (Fed Cir. 1985). They are not, however, conclusive. Fromson, supra, 755 F.2d at 1557; Leinoff v. Louis Milona & Sons, Inc., 726 F.2d 734, 740 (Fed. Cir. 1984). Secondary considerations "without invention will not make patentability." Anderson's - Black Rock, supra, 396 U.S. at 61, quoting A. & P. Tea Co., supra, 340 U.S. at 153.

Here, plaintiffs set forth but one secondary consideration for the

court's review, arguing that the perceived long-felt need for a more effective, safer dentifrice for sensitive teeth reveals the nonobviousness of the Hodosh solution in light of the prior art references here under consideration. See Shklar Aff. ¶ 4(C), at 7-11 and Exhs. 3-5. They might also have pointed to evidence of defendants' development of Promise Toothpaste based upon the knowledge acquired from the Hodosh patent, Plaintiff's App. 32-43, and the conceded commercial success of toothpastes for sensitive teeth including potassium nitrate. See Defendants' Letter Memorandum (10/2/84) at 2. Together, these factors constitute classic secondary considerations and argue persuasively that the Hodosh

patent ought not be found invalid on obviousness grounds. See generally 2 Chisum, supra, § 9.05, at 9-58 - 9-69; Dunner, Gambrell, Adelman & Lipsey, 1 Patent Law Perspectives § 2.6[6], at 2-606.2 - 2-652.1 (2d ed. 1985).

However, the court continues to find that the Hodosh patent is invalid on grounds of obviousness; these secondary considerations stem not from the novelty or inventiveness engendered by substituting potassium nitrate in an already existing formula, but from a lack of knowledge on the part of those in the field of the references here cited. That lack is here overcome by the presumption of omniscience discussed, supra, a rule of law by which the court is bound, whatever its mer-

its. See Shapiro, Toward a Realistic Standard of Patentability, 16 IDEA 3 (1974) (criticizing the "insidious presumption of inventor omniscience"). Had persons of ordinary skill in the pertinent arts known of these references, the court is persuaded, such long-standing need would have long ago been fulfilled, rendering copying unnecessary and commercial success

merely continuous.[8] The obviousness of substituting KNO_3 for strontium chloride is clear once such knowledge

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[8] This position is strengthened by the fact that it is plaintiff Hodosh who alluded to the Chinese references in his German patent application.

Additionally, it should be noted that, because these references were not cited to the Patent and Trademark Office, the normal presumption in favor of validity, see 35 U.S.C. § 282, is weakened, although the burden of proving invalidity remains on defendants. See, e.g., Kwik-Site Corp. v. Clear View, supra, 758 F.2d at 176, National Business Systems, Inc. v. AM International, Inc., 743 F.2d 1227, 1230 (7th Cir. 1984); Jervis B. Webb Co. v. Southern Systems, Inc., 742 F.2d 1388, 1392-93 (Fed. Cir. 1984) (citing cases); Northern Engineering & Plastics Corp. v. Eddy, 652 F.2d 333, 337-38 (3d Cir. 1981), cert. denied, 454 U.S. 1146 (1982). Of course, the degree to which such presumption is weakened "depends on a balancing of the pertinence of the newly cited art against the pertinence of the art actually considered by the Patent Office." Aluminum Co. of America, supra, 552 F.2d at 1024-25. Here, however, plaintiffs have not disclosed precisely what prior art was considered, either initially or on re-examination, or argued that such art renders the prior art cited by defendants insignificant.

is possessed. For this reason, even in light of the secondary considerations cited and those not cited by plaintiffs, defendants' motion for summary judgment of patent invalidity must be granted. See, e.g., Dickey-John Corp. v. International Tapetronics Corp., 710 F.2d 329, 346 (7th Cir. 1983); Aluminum Co. of America v. Amerola Products Corp., supra, 552 F.2d at 126.

CONCLUSION

For the aforestated reasons, the court finds the Hodosh patent to be invalid on grounds of obviousness. It need not, therefore, address the fascinating question of patent misuse raised by plaintiffs' contributory infringement claim. The court notes its doubts

as to whether defendants' product, Promise Toothpaste for Sensitive Teeth, can truly be regarded as "a staple article . . . of commerce suitable for substantial noninfringing use," 35 U.S.C. § 271(c), and, as such, beyond plaintiffs' "limited power to exclude others from competition in nonstaple goods." Dawson Chemical Co. v. Rohn & Haas Co., 448 U.S. 176, 201 (1980). Indeed, the evidence before the court tends to confirm the fact that defendants' toothpastes have been marketed as specialty products designed particularly for sensitive teeth, and that they have been priced, and regulated, accordingly. At most, therefore, an issue of fact appears to exist regarding whether there is a substantial

use for defendants' product that would not infringe plaintiffs' patent were it valid. However, the court need not and does not here address such issue at all, let alone with the complexity which it deserves, for it finds plaintiffs' patent to be invalid as obvious.

Defendants' motion for summary judgment on grounds of patent invalidity is granted. Defendants' motion for summary judgment on grounds of patent misuse is dismissed as moot. An appropriate order will issue.

/s/ H. LEE SAROKIN, U.S.D.J.
H. LEE SAROKIN, U.S.D.J.

Date: June 14, 1985

Appendix A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

MILTON HODOSH AND RICHARDSON-VICKS, INC.,	)	
APPELLANTS,	)	
v.	)	Appeal No. 85-2607.
BLOCK DRUG COMPANY, INC., ET AL.,	)	
APPELLEES.	)	

DECIDED: March 24, 1986

Before RICH, DAVIS, and BALDWIN, Circuit Judges.

RICH, Circuit Judge.

This appeal is from the July 12, 1985, judgment of the United States District Court for the District of New Jersey, 226 USPQ 645, granting

summary judgment to Block Drug Company, Inc., et al. (Block) and holding that all six claims of patent No. 3,863,006 for "Method of Desensitizing Teeth" ('006 patent), issued to Dr. Milton Hodosh and licensed to Richardson-Vicks, Inc. (collectively, Hodosh), are invalid for obviousness under 35 USC 103. We reverse and remand.

Background

Tooth desensitizers reduce discomfort and pain caused by tooth hypersensitivity or exposed dentin, the portion of the tooth between the enamel and the pulp which includes a myriad of microscopic tubules. Persons suffering from this condition react painfully to hot or cold foods, citric acid or

sweets, or everyday chemical, thermal, or tactile stimuli including toothbrush contact.

Milton Hodosh, a practicing dentist for about thirty years, independently developed the claimed subject matter of the '006 patent and granted Richardson-Vicks an exclusive license to make, use and sell the claimed invention; the latter markets its tooth desensitizing toothpaste under the trademark "Denquel."

Claim 1 of the '006 patent[1/] reads:

1/ A certificate of reexamination confirming the patentability of claims 1-6 of the '006 patent was issued June 21, 1983, as a result of Hodosh's request for reexamination in 1982. Only one of the prior art references involved here, the Rosenthal patent, infra, was considered in the reexamination.

> The method of desensitizing hypersensitive dentin and cementum by applying thereto an agent the essential ingredient of which is a nitrate of one of the following alkali metals: potassium, lithium or sodium said nitrate comprising between 1 percent and 20 percent by weight of said agent.

The remaining claims appear in the opinion below.

Appellee Block has, since 1961, marketed a tooth desensitizing toothpaste, covered by its patent No. 2,112,483 (the Rosenthal patent) for "Strontium Ion Toothpaste" issued in 1964, under the trademark "Sensodyne". The Rosenthal patent and the '006 patent disclose toothpaste formulae which are the same except that the latter contains, as a desensitizing agent, potassium nitrate instead of the Rosenthal-Block strontium chloride.

After requesting and being denied a license under the '006 patent, Block developed its own potassium nitrate-containing tooth-desensitizing tooth-paste called "Promise" and "Sensodyne-F."[2/]

March 30, 1983, Hodosh sued Block alleging that hte sale of "Promise" and "Sensodyne-F" contributorily infringed and actively induced infringement of the '006 patent. Block

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2/ Block also initiated regulatory proceedings designed to delay or prevent Richardson-Vicks' marketing of "Denquel." Block, having allegedly failed to comply with Food and Drug Administration (FDA) procedures before marketing "Promise" and "Sensodyne-F" in competitive response to Richardson-Vicks' introduction of "Denquel," is currently defending itself in forfeiture proceedings initiated by the FDA.

answered and counterclaimed alleging patent misuse and consequent unenforceability of the '006 patent. On July 11, 1984, Block moved for summary judgment as to both misuse and patent invalidity. Oral argument was heard October 16, 1984, and decision was reserved. June 14, 1985, the reported decision was handed down granting the motion as to patent invalidity and dismissing the motion on misuse as moot, resulting in the judgment now on appeal.

The district court heard no expert testimony, but did hear arguments of counsel, receive briefs, review exhibits, and had before it declarations and affidavits from experts on both sides commenting on the eight prior art

references involved here, including the Rosenthal patent. The court determined that there were no genuine issues of material fact and concluded as a matter of law that the claims of the '006 patent were invalid under §103 because the Rosenthal patent disclosed each element claimed in the '006 patent except the potassium nitrate, which, in its view, was disclosed in two Chinese references, both based on ancient Chinese writings. The court also stated that six European references supported its conclusion of obviousness.

Because the appropriateness of summary judgment is determined on an analysis of the facts, First National Bank of Arizona v. Cities Service Co.,

391 U.S. 253 (1968), and because everything about these references, as a whole, see, e.g., Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138, 227 USPQ 543, 547-48 (Fed. cir. 1985), is important to our determination, we review the record and lay out the relevant portions of the references in some detail.

A. The Chinese References

1. The Grand Dictionary of Chinese Medicine and Drugs (The Grand Dictionary)

The Grand Dictionary, published in Hong Kong in 1963 and written in Chinese, is based on ancient Chinese compilations assembled roughly 500 years ago from works of physicians

going back 4000-5000 years. Only a portion of the 1963 Chinese text was before the court and is before us on appeal. For purposes of this litigation, that portion was translated into English by Block's translator, Roger Wei-Ming Tsao (Mr. Cao). Mr. Cao is a doctor of Chinese medicine and a bilingual tutor. Block's other expert, Dr. Stephen Wei, a professor of dentistry fluent in Chinese, concurred in that translation. The writings from which the Grand Dictionary was compiled are not in evidence nor are any earlier writings.

In a nutshell, the district court relied upon the Grand Dictionary because of its discussion of "xiao shi" to which the Grand Dictionary asso-

ciates the name "niter" and the chemical composition KNO_3 and the ability to cure, inter alia, tooth pain. The court's opinion was that this reference teaches the use of xiao shi, which is the same as niter and is therefore the same as potassium nitrate, to cure tooth pain; thus, the teachings of the Rosenthal patent and the Grand Dictionary show that the '006 invention would have been obvious.

The following discussion and quotations are part of an attempt to convey the nature of the Grand Dictionary. The translated portion of the Grand Dictionary is entitled "Niter." The text under the first sub-heading "Nomenclature" reads: "It was so named because it has the power to

consume various stones." Under "Other Names Stated in Classical Medical Books," the text reads "Mang Xiao (Bie-Lu), Bitter Xiao (Zhen-Quan), Flaming Xiao (Tu-Su) . . . and Xiao-Shi . . . ." Thereafter, following "Foreign Names," the Grand Dictionary reads: "Salpetrae, Salnitri (in Latin): Niter (in English); and Salpoter (in German)." One page later, "KNO_3" is listed under "Chemical Composition."

The portion upon which Block and the district court rely to show that this substance cures tooth pain is headed "Collective Statements" and reads:

> (Ming): Li-Shi-Zhen said: It cures summer infections and the catching of colds. It cures acute enteritis with

> severe vomiting, exertion through excessive sexual activity, black jaundice, chronic abdominal pain, conjunctivitis, headaches and tooth pain.

The next three or so pages of the Grand Dictionary list the ailments that this substance cures. An interesting but not atypical paragraph reads: "For curing the paralysis of the four limbs, leprosy or problems caused by Taoist stone eating." This substance also apparently cures indigestion, lack of energy, typhoid, cataracts, and much, much more. The Grand Dictionary compares what apepars to be various forms in which xiao shi is found, and the characteristics of each. An excerpt is:

> Pu-Xiao (Na_2SO_4) has the nature of water, tastes salty, and its flavor is cold. It

can only descend and cannot ascend. It is Yin within Yin -- that's why it can cleanse the accumulation in the gastrointestinal tract and can expel the San-Jiao devilish fire. Whereas Niter (KNO_3) has the nature of fire, tastes bitter and spicy, tastes slightly salty and has a flavor which is very warm, it's [sic] nature is ascending. It is fire within water. That's why it can break the accumulation and disperse hardness, and cure the febrile diseases.

2. Ben Cao Gang Mu

Ben Cao Gang Mu (Ben Cao) is a treatise on Chinese Medicine published in Hong Kong, in Chinese, in 1930, 1954 and 1965, but was originally written by Li-Shi-Zhen who lived during the Ming

Dynasty.[3/] Like the Grand Dictionary, only a portion of the Chinese text Ben Cao is in evidence and that portion was translated by Mr. Cao and Dr. Wei for purposes of this litigation. The district court relied upon Ben Cao because it disucsses "xiao shi," which the translation of Ben Cao states is "niter" and associates the ability to cure "tooth pain (Ya Tong or Ya Teng)."

It is important to note, and the district court appeared to accept the fact, that the portion of the Grand Dictionary relied upon was compiled during the Ming Dynasty of the 13th to

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[3/] The Ming Dynasty (1368-1644 AD) was marked by the restoration of traditional institutions in China and the development of the arts, especially porcelain, textiles, and painting.

15th centuries in Ben Cao Gang Mu so that the relevant portion of the Grand Dictionary is subsequently a restatement of Ben Cao with some modification by an unidentified author. The court stated that these two references "quote the same Ming Dynasty source as labeling KNO_3 for tooth pain."

The Ben Cao translation is entitled "Xiao-Shi (Niter)" and refers to the same "Other names" for this substance listed in the Grand Dictionary. With respect to the quoted sections above, the Ben Cao translation is nearly verbatim. It has this to say about tooth pain:

> Da Ming states: It cures summer infections and the catching of colds, acute enteritis with severe vomiting, exertion thru excessive sexual activity and black jaundice, chronic

abdominal pain, conjunctivitis, headache and tooth pain (Ya-Tong or Ya Teng).

Hodosh argues that summary judgment was inappropriate; issues of fact as to the meanings of xiao shi and ya tong remain because a skilled dental researcher would surely seek and obtain a complete translation of the Grand Dictionary and of the other ancient Chinese references and would read those references carefully. Hodosh also argues that the ancient references should be dismissed because a person skilled in the art would find them incredible and would regard them as a quagmire of medical and dental nonsense. It therefore takes issue with the court's holding quoted below which apparently precluded inquiry into the

accuracy of the references by one skilled in the art:

> [A]ttacks upon the translation leading up to the prior art references embodied in the Grand Dictionary of Chinese Medicine and Drugs . . . or upon Chinese medicine as a whole. . . . are not here regarded as particularly pertinent, since they require skill beyond the scope of the "experienced researcher in dental fields . . . ."

Hodosh relies heavily on its expert's, Dr. Shklar's, testimony about the Chinese references: "[T]hey represent in modern terms, materials that are rarely comprehensible and frequently contradictory in their literal terms. The materials are largely seen by contemporary medical scientists as absurd; no serious medical researcher would waste his or her time with

them."[4/] Hodosh also contests this holding by the district court:

> Nor, if it is true that KNO_3 alleviates tooth sensitivity, is such reference in the prior art rebutted by the existence of errors in the reference such as, for example, the claim that KNO_3 is a cure for "exertion through excessive sexual activity." Whatever the merits of the other aspects of the Chinese references, the fact that they reveal KNO_3 to be a cure for ya tong is what is dispositive here. The reference clearly discloses such function of potassium nitrate, albeit in the context of otherwise incredible, and even erroneous descriptions of the compound's quality.

[4/] Dr. Shklar is the Charles A. Brackett Professor of Oral Pathology at the Harvard School of Dental Medicine, and is an acclaimed expert in dentistry. He is also an expert on the history of dentistry and holds membership in the American Academy of the History of Dentistry.

With respect to the specific meaning of xiao shi as used in these references, Dr. Shklar and Hodosh's other expert, Mr. Yen, a professional translator of Chinese and English languages, stated that the compiler of the Grand Dictionary erred in associating potassium nitrate or niter with xiao shi. Mr. Yen states that he

> was not able to render one single precise version because various dictionaries contain different and even conflicting definitions. For example, Source of Words, a Chinese language dictionary, published by Commercial Press, Taiwan, which has editions dating back to 1915, defines "Xiao-Shi" as "Mang-Xiao" on page 1255, and under "Mang-Xiao" on page 1770, reference is made that "Mang-Xiao" is "Liu-Suen-Na," and on page 1523 "Liu-Suen-Na" is defined as sodium sulfate ($Na_2SO_4 10H_2O$).

Mr. Yen also stated that "Xiao-Shi could be more than one material and that more than one material may be represented by the term 'Xiao-Shi'."

Dr. Shklar concurred:

> In my opinion, therefore, the answer to the question: What was "Xiao-Shi," is that it represented many different materials which cannot be identified with certainty.
>
> * * *
>
> Thus, these Exhibits did not describe potassium nitrate to one skilled in the art any more than any of the hundreds of salts, ores and oxides that possess some of the enumerated properties.

In addition, Dr. Shklar stated: "It is insufficient to simply state, as the Block translator does, that 'Xiao-Shi' is 'niter,' and then cite a modern dictionary to 'establish' that 'niter' is potassium nitrate." With respect to

both the Grand Dictionary and Ben Cao, he stated that "the translator appears to have inserted the term 'niter' into the text where the phrase 'consumer of stones' actually belongs."

Block's arguments, on the other hand, in part based on the short affidavit of Mr. Wei, substantially follow the district court's opinion. Block also challenges the competence of Hodosh's experts stating that they "either had no knowledge or training in the Chinese language or Chinese medicine or were unfamiliar with dentistry or medicine generally." Block also emphasizes that the Chinese references correctly disclose many of potassium nitrate's characteristics, like burning with a violet flame, useability for

making signal fires and gun powder, and its water solubility; these three properties of xiao shi in the Chinese references definetely confirm, according to Block, that xiao shi is potassium nitrate, KNO_3.

B. The European Prior Art

This art is contained in six references and was not relied upon to any significant degree by Block or the district court. Hodosh scarcely mentions it on appeal, instead preferring to show the existence of genuine issues of material fact with respect to the Chinese references. After concluding that using potassium nitrate to cure tooth pain would have been obvious from Rosenthal in view of the Chinese art,

the court stated: "Such holding is strengthened by the European prior art which, while ambiguous because of the several conflicting definitions in the term 'niter,' at least suggest to one skilled in the art that potassium nitrate ought to be tried as a cure for tooth pain in general."

Block submitted no affidavits that addressed the substance of the European references. Hodosh's Dr. Shklar, on the other hand, stated why this art, part of the "humors, spirits and Alchemy of the Dark Ages" having whatever medicinal effect they did by virtue of their use of wine, opium, or other narcotic substances, would have been questioned by one skilled in the art. He specifically contends that

Block's translation of "nitre" is erroneous: "it is common knowledge that these terms means sodium carbonate and/or sodium carbonate-sodium bicarbonate mixture . . . ."

To afford a glimpse of the nature of these references, an interesting and typical excerpt, one quoted by the district court, based upon a statement by the long since deceased French surgeon Guy de Chauliac reads that "a mixture of 'cuttlebone, small white sea shells, pumice, burnt stag's horn, nitre, alum, rock salt, burnt roots of iris, aristolochia, and reeds' could create an effective dentifrice." (District court's emphasis.) Three of the European references are based on that statement. The district court noted the others:

> Additionally, a 1693 treatise by the British Professor of Physics William Salmon states that nitrum "held in the Mouth . . . immediately helps the Toothach, if burnt and used in a Dentifrice, it cleanses and whitens the Teeth." . . . Similarly, a reference work by Hardianus a Mynsicht, translated into English in 1682, describes a mixture, including "nitre" as a "tincture for the toothache." . . . Finally, Pliny the Elder, in his Historie of the World, The Second Tome, translated into English in 1601, describes the use of nitre to "easeth the toothach, if the mouth and gums be washed therwith," or if burned, as a dentifrice. [Reference to Exhibits omitted.]

With this description of both the Chinese and European references, and of what they represent as a whole, in hand, we consider the proper application of the Graham standards and their effect upon the propriety of summary judgment in this case. See

generally Graham v. John Deere, 373 U.S. 1, 17 (1966); Panduit Corp. v. Dennison Manufacturing Co., 774 F.2d 1082, 227 USPQ 337 (Fed. Cir. 1985).

OPINION

A. Summary Judgment

Summary judgment, in patent as in other cases, is appropriate where there is no genuine issue of material fact, and the movant is entitled to judgment as a matter of law. See Molinaro v. Fannon/Courier Corp., 745 F.2d 651, 653-54, 223 USPQ 706, 707 (Fed. Cir. 1984). The movant bears the burden of demonstrating the absence of all genuine issues of material fact, and the district court must view the evidence in a light most favorable to

the nonmoving party and draw all reasonable inferences in its favor. See United States v. Diebold, Inc., 369 U.S. 654, 655 (1962); Palumbo v. Don-Joy Co., 762 F.2d 969, 973, 226 USPQ 5, 7 (Fed. Cir. 1985). The party opposing summary judgment must show an evidentiary conflict on the record; mere denials or conclusory statements are not sufficient. Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd., 731 F.2d 831, 836, 221 USPQ 561, 564 (Fed. Cir. 1984). Summary judgment is authorized where it is quite clear what the truth is. Sartor v. Arkansas Natural Gas Corp., 321 U.S. 620, 627 (1944).

B. The Issues Below

The decision and opinion of the district court granting summary judgment dealt with two issues: the first was whether the '006 patent is invalid as anticipated under §102(b), the court holding it is not; and the second was whether the '006 patent is invalid for obviousness under §103, the court holding that it is. Hodosh of course appeals the summary judgment with respect to only the issue on which it lost -- obviousness -- and Block has not appealed. Because we are remanding for trial, however, we will comment briefly on anticipation to make it clear that we deem that question to have been conclusively disposed of in this case and because it is closely related to the obviousness issue.

1. Anticipation, §102(b)

We agree entirely with the district court's holding that the '006 patent is not invalid as anticipated because there is no issue of fact that none of the prior art references discloses every element of the claimed invention. This issue was, therefore, appropriately and properly disposed of by summary judgment.

We do not agree, however, with some of the district court's remarks about anticipation, in particular, that the unavailability of the Chinese references and whether one skilled in the art could locate them with "reasonable diligence" bears on whether those references anticipate the claimed subject

matter. Whether a reference is available as prior art and whether it anticipates (i.e., contains every claimed element) are separate questions. Moreover, the district court's determination that the references are unavailable for §102 purposes seems to be inconsistent with the approach subsequently taken by the district court in determining obviousness. The court later used these same references to support its holding that the claimed subject matter would have been obvious at the time the invention was made to one of ordinary skill in the art.

2. Obviousness, §103

Questions of material fact remain with respect to the meaning of

various terms used in the Chinese and European references and we therefore hold that summary judgment on the ground of obviousness of the claimed invention was improper.

The district court's statement that ya tong means tooth hypersensitivity as well as tooth pain is the resolution of a head-on factual controversy. The court improperly drew the inference against Hodosh, the nonmoving party, that a statement about ya tong made to the German Patent Office by Dr. Hodosh's German patent agent was made with knowledge of the Chinese references. The statement in question occurred seven years after the '006 patent issued in connection with Dr. Hodosh's counterpart German applica-

tion. The statement was: "The super-sensitivity of dentine has been known for a long time and can be traced back 4000 years to the Chinese where it was known as 'Ya Tong'." Hodosh in this suit disclaims this statement urging that it was factual error.

There is no evidence that the above statement was based on the Chinese references or that Dr. Hodosh conveyed this information to the German patent agent. The important fact question as to the meaning of ya tong cannot be overcome simply by styling this statement an admission binding on Hodosh. Hodosh is entitled, as Block essentially concedes, to rebut the statement with evidence to the contrary. Hodosh will have that chance at trial.

Nor does the statement in the affidavit of Block's expert, Dr. Wei, that ya tong means tooth hypersensitivity eliminate the presence the presence of the question of the meaning of ya tong. As the Supreme Court long ago observed, "Experience has shown that opposite opinions of persons professing to be experts, may be obtained to any amount . . . ." Winans v. New York and Erie Railroad Co., 62 U.S. 88 (1859). The substance of Dr. Skhlar's [sic] affidavit on behalf of Hodosh goes far beyond merely denying that ya tong means tooth hypersensitivity and thus is more than adequate to show an evidentiary conflict on the record with respect to this crucial point, thus precluding summary judgment. Cf. Union

Carbide Corp. v. American Can Co., 724 F.2d 1567, 1571, 220 USPQ 584, 587-88 (Fed. Cir. 1984).

Furthermore, a geniune issue of material fact exists with respect to the meaning of the terms nitre, nitrum, and nitri as used in the European references. Dr. Sklhar's [sic] affidavit is more than adequate to withstand the challenge of this summary judgment motion. A reasonable inference that these terms are sodium, as opposed to potassium, compounds is permissible; Hodosh has shown an evidentiary conflict on the record. The European references, Dr. Sklhar [sic] explained in his affidavit, are based on the 77 A.D. writings of Pliny the Elder, who understood these terms to mean "sodium

carbonate and/or a sodium carbonate-sodium bicarbonate mixture."

The obviousness determination here, given the existence of genuine material issues of fact with respect to the meanings of terms used in these references, is not suitably disposed to by summary judgment under the rules pertaining thereto. See generally Palumbo, supra, and Lemelson v. TRW, Inc., 760 F.2d 1254, 1260-61, 225 USPQ 697, 700-01 (Fed. Cir. 1985). The fact issues herein must be resolved by trial in which the conflicting views of the experts will be subject to the refining fire of cross examination, a more effective means of arriving at the legal conclusion of obviousness vel non than perusal of ex parte affidavits and dec-

larations of partisan experts lobbed at each other from opposing trenches.

We observe, for the benefit of the trial court, that we are totally unimpressed by Block's forensic device of comparing the Rosenthal prior art toothpaste formula and the Hodosh toothpaste example in parallel columns and then asserting, as though it were filled with significant meaning, that the "only difference is the use of potassium nitrate in place of strontium chloride," or that "the Hodosh patent merely substitutes potassium nitrate for strontium chloride." This device was pushed to the limit in oral argument by pointing out that the Hodosh toothpaste has the same formula, except for the active desensitizing ingredi-

ent, down to the last decimal point. This argument is meaningless on the obviousness issue. "Sensodyne" and apparently other desensitizing toothpaste formulae being well known as commercial products, it is entirely clear that Dr. Hodosh's invention was the discovery of an apparently superior desensitizing agent and he never thought it was a toothpaste formula. He made that invention even if it should later be decided that it was known to the Chinese. It is apparent that Hodosh's patent solicitor merely adopted the prior art Rosenthal toothpaste base formula as a convenient example to illustrate the kind of a paste in which the Hodosh desensitizer might be used, which was within his

right. The similarities -- indeed, identity -- of the paste bases is irrelevant in considering the issue of the unobviousness of the desensitizer. The Rosenthal patent, cited as prior art by Hodosh in his patent specification, was the jumping-off place for the description of his discovery. Hodosh does not claim to have been the first inventor of a desensitizing toothpaste; he claims to have improved it. The issue for trial is whether his

improvement would have been obvious.[5/]

[5/] Our comments on the district court's obviousness determination generally include the following tenets of patent law that must be adhered to when applying §103: (1) the claimed invention must be considered as a whole (35 USC 103; see, e.g., Jones v. Hardy, 727 F.2d 1524, 1529, 220 USPQ 1021, 1024 (Fed. Cir. 1984) (though the difference between claimed invention and prior art may seem slight, it may also have been the key to advancement of the art)); (2) the references must be considered as a whole and suggest the desirability and thus the obviousness of making the combination (see, e.g., Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co., 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984)); (3) the references must be viewed without the benefit of hindsight vision afforded by the claimed invention (e.g., W. L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)); (4) "ought to be tried" is not the standard with which obviousness is determined (Jones, supra, 727 F.2d at 1530, 220 USPQ at 1026); and (5) the presumption of validity remains constant and intact throughout litigation (35 USC 285; e.g., American Hoist and Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359-60, 220 USPQ 763, 770 (Fed. Cir. 1984)).

C. Secondary Considerations

The district court refused on the motion for summary judgment to consider the evidence of secondary considerations. After acknowledging its existence and the arguments based on it, it stated:

> However, the court continues to find that the Hodosh patent is invalid on grounds of obviousness; these secondary considerations stem not from the novelty or inventiveness engendered by substituting potassium nitrate in an already existing formula, but from a lack of knowledge on the part of those in the field of the references here cited. The lack is here overcome by the presumption of omniscience discussed, supra, a rule of law by which the court is bound, whatever its merits.

That secondary considerations are not considered unless there is

evidence that those in the industry knew of the prior art is a non sequitur. Evidence of secondary considerations is considered independently of what any real person knows about the prior art. These considerations are objective criteria of obviousness that help illuminate the subjective determination involved in the hypothesis used to draw the legal conclusion of obviousness based upon the first three factual inquiries delineated in Graham. Thus, to require that actual inventors in the field have the omniscience of the hypothetical person in the art is not only contrary to case law, see Kimberly Clark v. Johnson & Johnson, 745 F.2d 1437, 223 USPQ 603 (Fed. Cir. 1984), but eliminates a

useful tool for trial judges faced with a nonobviousness determination.

The secondary consideration evidence of record and the additional evidence likely to be submitted at trial must be considered in the obviousness determination. See generally Fromson v. Advance Offset Plate, Inc., 755 F.2d 1549, 1557, 225 USPQ 26, 36 (Fed. Cir. 1985).

Conclusion

The grant of summary judgment of invalidity is reversed and the case is remanded in accordance with this opinion.

REVERSED AND REMANDED

EDITOR'S NOTE

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Supreme Court, U.S.
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CLERK

No.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

BLOCK DRUG COMPANY, INC., et al.,

Petitioners,

vs.

MILTON HODOSH and RICHARDSON-VICKS, INC.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

APPENDIX

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United States Patent [19]

Hodosh

[11] **3,863,006**

[45] **Jan. 28, 1975**

[54] **METHOD FOR DESENSITIZING TEETH**

[76] Inventor: **Milton Hodosh**, 145 Whitemarsh St., Providence, R.I. 02906

[22] Filed: **Jan. 29, 1973**

[21] Appl. No.: **327,758**

[52] U.S. Cl. 424/49

[51] Int. Cl. A61k 7/16

[58] Field of Search 424/49-58

[56] **References Cited**

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Primary Examiner—Richard L. Huff

Attorney, Agent, or Firm—Salter & Michaelson

[57] **ABSTRACT**

A compound and method for desensitizing hypersensitive teeth, and specifically hypersensitive dentin and cementum, the essential ingredient of said compound comprising a nitrate of potassium, lithium or sodium, and the method comprising the application of said compound in aqueous solution or nontoxic paste form to the sensitive area.

6 Claims, No Drawings

METHOD FOR DESENSITIZING TEETH

BACKGROUND AND SUMMARY OF THE INVENTION

The present invention relates to a compound and treatment for eliminating or, at the very least, greatly reducing, discomfort and pain caused by tooth hypersensitivity or exposed cementum and/or dentin.

It is becoming increasingly apparent that the problem of tooth hypersensitivity affects a far greater number of people than previously suspected. People suffering from this annoying condition may react painfully to heated or chilled foods, citric acid or sweets, or other every-day stimuli, including toothbrush contact. The problem is especially prevalent in adults who have lost some of the normal protective enamel sheathing on tooth surfaces because of erosion, abrasion, caries, chipping of the enamel, or in whom recession of the gingiva has exposed tooth dentin and/or cementum. However, tooth hypersensitivity is now being found to exist even in the absence of any of the foregoing.

Attempts have heretofore been made to eliminate or at least reduce the painful effects of tooth hypersensitivity or of exposed cementum and/or dentin; but, for various reasons, many of these previous attempts have not been completely successful. For example, silver nitrate is a known desensitizer, but it is such a powerful oxidant that it may burn or otherwise irritate the gum tissues, as well as causing discoloration of the teeth. In another approach, a finely ground paste of dicalcium acid phosphate was rubbed into the exposed, sensitive tooth roots of various patients suffering from hypersensitivity with some success, based on the observation that the paste crystallized and blocked the dentinal tubules, thereby apparently protecting the sensitive, nerve-filled pulp inside. Still another approach involves the use of strontium ions, as disclosed in U.S. Pat. No. 3,122,483 dated Feb. 25, 1964.

In spite of the above, the search goes on for a desensitizer which may be easily and economically produced, which may be easily applied to hypersensitive tooth areas, which is effective in achieving the desired desensitizing function without irritation of the gums and discoloration of the teeth, and which has a longer lasting effect. It is to the accomplishment of these objectives that the present invention is directed.

DESCRIPTION OF THE INVENTION

It has been found that the nitrate of any one of the following alkali metals has amazing and unusual desensitizing action when applied to hypersensitive teeth or exposed dentin and/or cementum. Specifically, potassium nitrate, lithium nitrate, and sodium nitrate have been found to be extremely effective in this regard, and potassium nitrate, in particular, has been found to be both extremely effective and relatively long lasting in its effect. However, lithium nitrate and sodium nitrate are also effective, and none of these nitrates are irritating to the gingiva, nor do they discolor the teeth. Other potassium salts have been tried, but none appear to be as effective as potassium nitrate insofar as desensitizing is concerned. Also, other metal nitrates do not seem to be as effective and satisfactory. Thus, for reasons not completely known, potassium nitrate achieves an unusually effective desensitizing result, and to a somewhat lesser extent, so do the other alkali metal nitrates, namely, lithium nitrate and sodium nitrate.

The other alkali metals, namely, rubidium, cesium, and francium, are extremely rare and expensive and hence are not feasible nor practicable for use in the present invention. In addition, francium is radioactive.

In utilizing potassium nitrate as a desensitizing agent, it is simply necessary to dissolve potassium nitrate crystals in a liquid solution, preferably water; and then the solution so formed is liberally applied to the hypersensitive area by means of cotton or the like. It has specifically been found that an aqueous solution comprising 5 percent by weight of potassium nitrate works extremely well. On the other hand, an aqueous solution comprising 1 percent by weight of potassium nitrate is also effective, but not to the extent that a more concentrated solution is. An aqueous solution of potassium nitrate saturates when the solution contains approximately 20 percent by weight potassium nitrate, and such a saturated solution may also be used, but the results of a saturated solution are not sufficiently beneficial over that of a 5 percent solution to justify the inclusion of the additional potassium nitrate.

As previously stated, the liberal application of an aqueous solution of potassium nitrate to the hypersensitive area results in almost immediate and extremely pronounced desensitization of the hypersensitive area, without any irritation of the gingiva, nor any discoloration of the teeth. In addition, the desensitization effect remains for a relatively long time, and in some cases for days.

In addition to applying the nitrate of potassium, lithium or sodium to the hypersensitive area in the form of an aqueous solution, it is also possible to incorporate the nitrate in a nontoxic paste which would then be applied to the sensitive area. For example, a paste was formulated as follows:

	Percent
Potassium nitrate	10.0
Water	34.2
Glycerin	25.0
Hydroxyethylcellulose	1.6
Polyoxyethylene sorbitan monolaurate	2.0
Micronized silica	24.0
Spearmint oil	1.0
Saccharin	0.2

(All percentages by weight)

The above paste, which actually has ingredients to function as a toothpaste in addition to performing a desensitizing function, when applied to a hypersensitive area in a patient's mouth, achieves basically the same desensitizing results as where the application is by means of an aqueous solution. More specifically, relatively extreme desensitizing took place without any irritation of the gingivae or discoloration of the teeth. When used in a paste of this type, the compound obviously has a preventive function, as well as a treatment function.

Although it is not positively known whether the desensitizing effect of the potassium nitrate is due to the oxidizing nature of the compound, or whether a crystallization takes place which blocks the dentinal tubules and hence protects the sensitive, nerve-filled pulp located therein, the fact remains that the use of potassium nitrate, and also lithium and sodium nitrate, whether in aqueous or paste form, results in desensitization of the hypersensitive area to an unexpected and

surprising degree without adversely affecting said area in any way, and said desensitizing effect has been found to be relatively long lasting.

As this invention may be embodied in several forms without departing from the spirit or essential characteristics thereof, the present embodiment is therefore illustrative and not restrictive, since the scope of the invention is defined by the appended claims rather than by the description preceding them, and all changes that fall within the metes and bounds of the claims or that form their functional as well as conjointly cooperative equivalents, are therefore intended to be embraced by these claims.

What is claimed is:

1. The method of desensitizing hypersensitive dentin and cementum by applying thereto an agent, the essential ingredient of which is a nitrate of one of the following alkali metals: potassium, lithium or sodium said nitrate comprising between 1 percent and 20 percent by weight of said agent.

2. The method of claim 1 further characterized in that said nitrate is potassium nitrate in an aqueous solution.

3. The method of claim 2 further characterized in that said potassium nitrate comprises approximately 5 percent (5%) by weight and saturation of said aqueous solution.

4. The method of claim 1 further characterized in that said nitrate is potassium nitrate mixed with a nontoxic paste.

5. The method of claim 4 further characterized in that said potassium nitrate comprises approximately ten percent (10%) by weight of said paste.

6. The method of desensitizing hypersensitive dentin and cementum by applying thereto an aqueous solution, the essential ingredient of which is potassium nitrate, said potassium nitrate comprising between 1% by weight and saturation of said aqueous solution.

* * * * *

United States Patent Office 3,122,483 Patented Feb. 25, 1964

3,122,483

STRONTIUM ION TOOTHPASTE

Murray W. Rosenthal, East Brunswick, N.J., assignor to Block Drug Company, Inc., Jersey City, N.J., a corporation of New Jersey

No Drawing. Filed July 22, 1960, Ser. No. 44,246
11 Claims. (Cl. 167—93)

The present invention relates generally to an improved dentrifice, and in particular it relates to an improved paste dentrifice effective in the treatment of hypersensitive dentin.

The condition known as hypersensitive dentin is quite prevalent. It may exhibit itself in response to various external stimuli on the surface of the teeth such as thermal changes, tactile stimuli, high osmotic pressures in the oral cavity, changes in pH, and other common circumstances virtually impossible to avoid. The problem is especially acute in adults who have lost some of the normal protective enamel sheathing on tooth surfaces because of erosion, abrasion, caries, chipping of the enamel, or in whom recession of the gingiva has exposed tooth dentin and cementum. However, certain stimuli such as cold, heat, and high sugar concentrations may evoke a painful response in children's teeth even when the teeth are in sound condition and the protective enamel tooth covering is still intact. The causes of painful hypersensitive dentin have never been completely explained since it has been demonstrated that calcified tooth structure itself does not contain nerve fiber. However, a generally accepted theory is that the dentinal tubules and odontoblastic fibrils in dentin, the normal functions of which are to produce calcified compounds in the tooth structure, are capable of transmitting neural impulses from the tooth structure to the dental pulp, which contains extremely sensitive nerve cells. The dentinal tubules and odontoblastic fibrils account in large part for the organic fraction of tooth dentin. It is known that both immature enamel and immature and mature dentin are higher in organic content than mature enamel, and thus probably have a higher content of dentinal tubules and odontoblastic fibrils than tooth enamel for the transmission of the above mentioned neural impulses. This circumstance would explain the greater sensitivity of immature teeth and exposed dentin in mature teeth.

Many methods have been proposed for the treatment of hypersensitive dentin. Some of these include sodium fluoride solution, sodium silicofluoride solution, zinc chloride solution, formaldehyde solution, concentrated glycerin, silver nitrate solution, and other agents. However, all these proposed therapies suffer from one disadvantage or another. Some are potentially toxic to the user if accidentally ingested in large doses; others are tissue denaturants or coagulants to be used with great caution and only under professional supervision, and others may discolor the teeth. None are believed to be suitable for incorporation into a toothpaste for home use which would be effective, stable, and safe for continued periods of time.

It is, therefore, a principal object of the present invention to provide an improved dentifrice.

Another object of the present invention is to provide an improved paste dentifrice effective in the treatment of hyper-sensitive dentin.

Still another object of the present invention is to provide paste dentifrice compositions which will carry solutions of strontium compounds capable of releasing strontium ions to the calcified structures of the human teeth.

A further object of the present invention is to provide a means for individuals to bring into contact with their

teeth toothpaste containing solutions of water-soluble strontium compounds.

Still a further object of the present invention is to provide novel compositions of matter in the form of toothpastes which will allow the calcified tissues of the human mouth to adsorb strontium ions from solutions of water-soluble strontium compounds contained in the toothpaste.

An additional object of the invention is to provide a convenient, rapid, non-toxic, therapeutic method for the daily treatment and control of painful dentin, commonly known as hyper-sensitive dentin, by use of a toothpaste which releases strontium ions from solutions of water-soluble strontium compounds contained in the toothpaste during normal toothbrushing procedures.

Other objects and advantages of the invention will be apparent to those skilled in the art.

It has been discovered that solutions of water-soluble strontium compounds are particularly suitable for the therapy of hyper-sensitive dentin and are non-injurious to the tissues of the mouth. When applied to tooth surfaces, it is believed that an adsorption of strontium ions occurs on the odontoblastic fibrils or in the dentinal tubules thus blocking the transmission of neural impulses from the dentinal surface to the dental pulp. Since strontium ion is a normal constituent of tooth structure and since it has extremely low local and systemic toxicity, it is believed that this observation provides a useful therapeutic means for the dentist to control hypersensitive dentin by the application of simple water-soluble strontium compound solutions to the teeth of his patients.

The use of a surface active wetting agent with the water soluble strontium compound contained in the toothpaste has been found to be highly desirable, particularly when such wetting agent is a foaming type of detergent. In addition to serving the purpose of cleaning the teeth, the detergent enhances the effectiveness of the strontium ion as a desensitizing agent by facilitating penetration of strontium ions into tooth structure. The water-soluble strontium compound is advantageously incorporated along with the wetting agent in a toothpaste which includes enough water to dissolve a substantial percentage, or all, of the water-soluble strontium compound, a polishing agent and certain other ingredients including bodying and gelling agents, and other additives.

The incorporation of water-soluble strontium compounds in common water-containing toothpaste formulations so that treatment for hypersensitive dentin can be continued away from the dental office, however, has heretofore proven to be wholly unsuccessful because of the highly reactive chemical nature of the strontium ion. Most commercial dentifrices are formulated with inorganic chemical polishing agents of low solubility in which the cation is an alkaline earth metal such as calcium or magnesium. Calcium phosphates, calcium carbonate, calcium sulfate, magnesium hydroxide, magnesium phosphates, and magnesium carbonate are examples of commonly used polishing compounds. It is not feasible to incorporate water-soluble strontium compounds into water-containing toothpaste formulations of this nature because of the chemical reaction which will occur between the strontium ions from the water-soluble strontium compound and the anions of the alkaline earth metal polishing agent in the presence of water contained in the toothpaste with eventual partial to complete precipitation and removal from therapeutic utility of the originally soluble strontium compound.

Furthermore, the foaming agents used in normal tooth paste formulations are surface active wetting agents which are usually anionic in nature, consisting of long-chain fatty

fatty acid soaps, and fatty acids or alcohols etherified, esterified, or condensed with sulfates, phosphates, amino acids, polyalkylene oxides, or conjugated cyclic derivatives. Strontium ions will react with many of these surfactants in the presence of water contained in a toothpaste to produce insoluble strontium derivatives which can not then provide the cleansing and foaming action desirable in toothpastes after storage for prolonged periods.

In addition, many of the bodying and gelling agents employed in conventional toothpaste formulations are alkali-metal salts of high molecular weight carbohydrate or cellulosic polymers containing terminal carboxylic or sulfonic acid groups. These agents are not suitable for use with water-soluble strontium compounds held in solution because of the eventual reaction between the acid radicals with the strontium ion in the presence of water contained in the toothpaste, resulting in a loss of bodying properties in the finished toothpaste.

It has been found to be essential, therefore, to incorporate the water-soluble strontium compounds into water-containing toothpastes in which all major components are compatible with the strontium compounds; that is, that such toothpaste components will neither render inactive nor precipitate the strontium ion and the word compatible will herein be used in such sense both in the specification and in the appended claims. Examples of compatible polishing agents which have been employed for the purpose include strontium phosphates, strontium carbonate, micronized silica, and aluminum hydroxide. Examples of surface-active foaming agents which have been employed, demonstrating a high degree of compatibility with water-soluble strontium compounds, include the polyoxyethylene partial esters of polyhydric fatty acid derivatives, polyoxyethylene polyoxypropylene condensates, polyoxyethylene-fatty alcohol ethers, fatty acid N-methyl taurine condensates, and the like. Examples of compatible bodying agents which have been used include methylcelluloses, hydroxyethylcelluloses, and very high molecular weight polyoxyethylene polymers.

Other constituents incorporated in the water-containing toothpastes must also be compatible with water-soluble strontium compounds. For that reason, sodium benzoate is not used as a preservative since it will react with strontium ions in the presence of water contained in the toothpaste to produce an insoluble precipitate. Ascorbic acid, sodium bicarbonate, sodium N-lauroyl sarcosinate, sodium oxalate, sodium lauryl sulfate, sodium fluoride, stannous fluoride, diammonium phosphate, water-soluble chlorophyllins, antibiotics with free carboxylic groups, and many other compounds which have been suggested for toothpaste formulation, are similarly unusable because of their potential reaction and precipitation with strontium ion in the presence of water contained in the toothpaste.

Examples of water-soluble ionic strontium compounds that may be employed satisfactorily for the present purpose include strontium chloride, strontium acetate, strontium bromide, strontium lactate, strontium iodide, strontium nitrate, and strontium salicylate. However, the choice of the particular anion in the original dry strontium compound will be apparent from the above to those skilled in the art. The limiting circumstances are that the strontium compound used be non-toxic, that it be water-soluble, that it can be dissolved in the water contained in the toothpaste, and that it contribute strontium ions to the aqueous solution in which it is used. When the term "ionic" strontium compound is employed, what is meant is a strontium compound which provides strontium ions when in aqueous solution. When the term "water-containing" toothpaste is employed, what is meant is a dentifrice in semi-solid or viscous, liquid form which has been compounded with enough water to dissolve a substantial percentage or all of the strontium compound contained therein.

The concentration of the strontium ions employed in compatible toothpaste compositions should range from between about 0.5% to 10.0% and the surface-active wetting agent from about 0.5% to 5.00%. Concentrations of strontium ions lower than the stated minimum will have little effect in relieving hypersensitive dentin. Amounts in excess of 10% will result in salty and bitter toothpastes, rendering them unpalatable, although not detracting from their therapeutic utility. More particularly, it has been found that the range of 2.0% to 5.0% of strontium ions and 1.0% to 3.0% of the wetting agent to be preferable concentrations to exert the desired therapeutic effect. The compatible polishing agent should preferably be present by weight between about 10% and 50%. The amount of water used in the toothpaste composition should be great enough to dissolve a therapeutically active concentration of the water-soluble strontium compound within the limits set forth above.

As examples of toothpastes in accordance with the present invention, the following are offered for illustrative purposes, percentages being given by weight:

EXAMPLE 1

	Percent
Strontium chloride.6 H_2O	[1] 10.0
Water	36.2
Glycerin	25.0
Hydroxyethylcellulose	1.6
Polyoxyethylene sorbitan monolaurate	2.0
Micronized silica	24.0
Spearmint oil	1.0
Saccharin	0.2

[1] Equivalent to 3.3% strontium ion concentration.

EXAMPLE 2

	Percent
Strontium lactate.3 H_2O	[1] 8.0
Water	36.2
Strontium carbonate	15.0
Sodium N-lauryl N-methyltaurate	2.5
Sorbitol	20.0
Micronized silica	15.0
Methylcellulose	2.0
Peppermint oil	0.8
Dulcin	0.5

[1] Equivalent to 2.6% strontium ion concentration.

EXAMPLE 3

	Percent
Strontium acetate.½ H_2O	[1] 10.0
Water	27.00
Aluminum hydroxide	26.0
Micronized silica	10.0
Glycerin	22.0
Polyoxyethylene polymer (molecular weight about 2,000,000)	1.3
Polyoxyethylene lauryl ether	2.0
Spearmint oil	0.9
Methyl salicylate	0.1
Methyl para-hydroxybenzoate	0.05
Saccharin	0.15

[1] Equivalent to 4.2% strontium ion concentration.

EXAMPLE 4

("Liquid" Toothpaste)

	Percent
Strontium bromide.6 H_2O	[1] 20.0
Water	63.6
Micronized silica	10.0
Methylcellulose	2.0
Methyl parahydroxybenzoate	0.07
Propyl parahydroxybenzoate	0.03
Polyoxyethylene sorbitan monostearate	3.0
Spearmint oil	0.7
Peppermint oil	0.3
Saccharin	0.3

[1] Equivalent to 4.9% strontium ion concentration.

All of the above mentioned compositions are adequate cleansers for the human dentition and may be used for the ordinary purposes of removing superficial stains and food particles from and between the teeth, and for refreshing and sweetening the mouth. They differ from usual toothpaste formulations, however, in that in the presence of water contained in the toothpaste carrier, they release strontium ions which can connect and adsorb on the organic structure of dentin and thereby exert a protective effect against the transmission of sensory impulses from the exterior surfaces of the teeth to the dental pulp.

It should be noted that in the examples given above that the various ingredients thereof may be substituted in whole or in part by one or more of the similarly functioning substances earlier set forth and that the concentrations of these ingredients may be varied within the ranges earlier indicated.

While there has been described preferred embodiments of the present invention, it is apparent that numerous alterations, omissions and additions may be made without departing from the spirit thereof.

I claim:

1. A water-containing toothpaste comprising a substantially stable solution of a non-toxic, water-soluble ionic strontium compound and a surface-active wetting agent compatible with strontium ions in an aqueous solution, said toothpaste being characterized by the substantial absence of substances which precipitate said strontium.

2. The toothpaste of claim 1, wherein said surface acting wetting agent is selected from the class consisting of polyoxyethylene partial esters of polyhydric fatty acid derivatives, polyoxyethylene polyoxypropylene condensates, polyoxyethylene-fatty alcohol ethers and fatty acid N-methyl taurine condensates.

3. The toothpaste of claim 1, including a polishing agent selected from the class consisting of strontium phosphate, strontium carbonate, micronized silica and aluminum hydroxide.

4. The toothpaste of claim 1, wherein said strontium compound is selected from the class consisting of strontium chloride, strontium acetate, strontium bromide, strontium lactate, strontium iodide, strontium nitrate and strontium salicylate.

5. The dentifrice of claim 1, including a bodying agent selected from the class consisting of methylcellulose, hydroxyethylcellulose and polyoxyethylene polymers.

6. A water-containing toothpaste comprising a substantially stable solution of a non-toxic, water-soluble ionic strontium compound and a surface-active wetting agent compatible with strontium ions in an aqueous solution, said strontium ions constituting between 0.5% and 10% by weight of said toothpaste, said toothpaste being characterized by the substantial absence of substances which precipitate said strontium.

7. A toothpaste in accordance with claim 6, wherein said wetting agent constitutes between 0.5% and 5% by weight of said toothpaste.

8. A toothpaste in accordance with claim 7, including between 10% and 50% by weight of said toothpaste of a polishing agent compatible with strontium ions in an aqueous solution.

9. A water-containing toothpaste comprising a substantially stable solution of an ionic strontium compound selected from the class consisting of strontium chloride, strontium acetate, strontium bromide, strontium lactate, strontium iodide, strontium nitrate and strontium salicylate, a surface active wetting agent compatible with strontium ions in an aqueous solution and selected from the class consisting of polyoxyethylene partial esters of polyhydric fatty acid derivatives, polyoxyethylene polyoxypropylene condensates, polyoxyethylene-fatty alcohol ethers and fatty acid N-methyl taurine condensates, and a polishing agent compatible with strontium ions in an aqueous solution, said strontium ion constituting between 0.5% and 10% by weight of said toothpaste, said toothpaste being characterized by the substantial absence of substances which precipitate said strontium.

10. A toothpaste in accordance with claim 9, including a bodying agent compatible with said strontium ion.

11. A water-containing toothpaste comprising a solution of a non-toxic strontium compound providing strontium ions, a surface active wetting agent, a polishing agent, and characterized by the substantial absence of substances incompatible with the strontium ions in an aqueous solution.

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Supreme Court, U.S.
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CLERK

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No. 85-2119

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

BLOCK DRUG COMPANY, INC., et al.,

Petitioners,

vs.

MILTON HODOSH and RICHARDSON-VICKS, INC.,

Respondents.

BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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COUNTERSTATEMENT OF QUESTION PRESENTED

Did the Court of Appeals err by unanimously reversing the District Court's grant of summary judgment of patent invalidity for obviousness because of the existence of genuine issues of material facts?

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THE CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED

35 U.S.C. §103

> Conditions for patentability; non-obvious subject matter
>
> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

F. R. Civ. P. 56(c)

> Rule 56. Summary Judgment
>
> (c) Motion and Proceedings Thereon. The motion shall be served at least 10 days before the time fixed for the hearing. The adverse party prior to the day of hearing may serve opposing affidavits. The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. A summary judgment, interlocutory in character, may be rendered on the issue of liability alone although there is a genuine issue as to the amount of damages.

Statement Pursuant to Rule 28.1

Petitioners: Block Drug Company, Inc.
Block Drug Corporation
Dentco, Inc.

Respondents: Milton Hodosh
Richardson-Vicks, Inc.
Parent: Procter & Gamble, Inc.
Partially owned subsidiaries:
Richardson-Hindustan Limited (India)
Vick Nigeria Limited
Vidal Sassoon – MSJ (Hong Kong)
York Avenue Beauty Salons, Ltd. (Canada)
P.T. Richardson-Vicks Indonesia

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MILTON HODOSH and RICHARDSON-VICKS, INC.,

Respondents.

BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

COUNTERSTATEMENT OF THE CASE

Dr. Hodosh's patent was granted, and confirmed on reexamination, for his discovery that potassium nitrate is a superior agent for the treatment of dental hypersensitivity.[1] Dr. Hodosh and Richardson-Vicks, his exclusive licensee, sued Block for infringement of that patent. Block moved for summary judgment on the

[1] Persons suffering from dental hypersensitivity react painfully to hot and cold foods, citric acid or sweets or everyday thermal or tactile stimuli, including toothbrush contact.

ground that Dr. Hodosh's patent was invalid in view of the prior art. A unanimous panel of the Court of Appeals for the Federal Circuit reversed the District Court's grant of summary judgment because of the existance of genuine issues of material fact.

The principal issues of material fact on Block's motion relate to the meaning of certain Chinese terms ("Xiao-Shi" and "Ya-Tong") and the credibility of certain Chinese references. Block's motion for summary judgment relied principally on two Chinese texts that are the work of Li-Shi-Zhen and date from the Ming Dynasty (1368-1644 A.D.). The texts are the *Grand Dictionary of Chinese Medicine* (1963) and *Ben Cao Gang Mu* (1965). The relevant portion of the *Grand Dictionary* purports to be a reprint of portions of *Ben Cao Gang Mu* and both texts contain the following passage which was translated to English and relied on by Block:

> It ["Xiao-Shi"] cures summer infection and the catching of colds. It cures acute enteritis with severe vomiting, exertion through excess sexual activity, black jaundice, chronic abdominal pain, conjunctivitis, headaches, and ["Ya-Tong"].

Block submitted affidavits of a translator and a dentist of Chinese descent to support its position that "Xiao-Shi" means potassium nitrate, and that "Ya-Tong" means toothpain including dental hypersensitivity. Belatedly, Block also submitted a statement made by Dr. Hodosh's German patent agent concerning the meaning of "Ya-Tong" to support its position. Dr. Hodosh submitted affidavits of a translator, a physician and an acclaimed expert in dentistry and the history of dentistry. The affiants supported Dr. Hodosh's position that "Xiao-Shi" does not have a definite meaning, but includes many different materials; that "Ya-Tong" does not include dental hypersensitivity; and that the

Chinese references were incredible to one skilled in this art.[2]

The District Court accepted the conflicting affidavits as evidence, yet held that there was no genuine issue of material fact, and granted Block's motion for summary judgment that the patent was obvious under 35 U.S.C. § 103.

The unanimous Court of Appeals reversed and held that the various references and affidavits presented genuine issues of material fact regarding translation, interpretation and credibility which precluded summary judgment. The Court of Appeals remanded the case for trial. Block now seeks a Writ of Certiorari to review the order of the Court of Appeals.

---

[2] Even the District Court agreed with Dr. Hodosh's position that the Chinese references are "incredible and even erroneous" (App. at 64a).

The Court of Appeals noted that:

> An interesting but not atypical paragraph reads: 'For curing the paralysis of the four limbs, leprosy or problems caused by Taoist stone eating.' This substance apparently cures indigestion, lack of energy, typhoid, cataracts, and much, much more. (App. B, p. 88a.)

SUMMARY OF ARGUMENT

Block's Petition asks this Court to exercise its Certiorari jurisdiction so that this Court may weigh the competing evidence of record to determine whether material questions of fact exist in this case. This would be an inappropriate use of the Court's resources and would be contrary to the Court's policy of only granting a Writ of Certiorari in cases which involve inter-circuit conflicts or compelling questions of federal law.

Block's arguments in support of its Petition distort the record below so as to make it seem that the Court of Appeals reached its decision by ignoring Block's evidence and the teaching of the references. In truth, the Court of Appeals gave full consideration to the Chinese references of record without regard to their age and made careful note of the abundant "rebuttal evidence" introduced by Dr. Hodosh. The Court of Appeals properly remanded this case for trial "in which the conflicting views of the experts will be subject to the refining fire of cross examination" (App. at llla).

The Writ should not be granted.

REASONS WHY THE WRIT SHOULD NOT BE GRANTED

A. *This Court Should Not Exercise Its Certiorari Jurisdiction to Consider Whether, in a Particular Case, Genuine Issues of Material Fact Exist Which Preclude Summary Judgment*

Block does not question the legal principles concerning summary judgment under F.R.Civ.P. 56(c), or the tenets of patent law which were applied by the Court of Appeals. Instead, Block's Petition rests on arguments about the sufficiency, persuasiveness, or supposedly conclusive nature of the competing evidence. Reduced to its essentials, Block's Petition asks this Court to exercise its Certiorari jurisdiction solely to consider whether the record in this case establishes that Dr. Hodosh came forward with sufficient evidence to show that there are genuine issues of material fact which must be resolved at trial. Thus, the Petition is devoid of significant legal questions, much less a showing of "special and important reasons" to justify the issuance of a Writ of Certiorari (See Supreme Ct. Rule 17.1).

Not even Block contends that denial of summary judgment because of the existence of genuine issues of material fact in this case creates a conflict between Circuits on an important question of Federal law. Further, the proceedings below were entirely regular, and Block does not accuse the Court of Appeals of "depart[ing] so far from the accepted and usual course of judicial proceedings ... as to call for an exercise of this Court's power of supervision." (*id.*) Finally, it cannot be contended that the question of whether the affidavits of competing experts as to the translation, interpretation, and credibility of Chinese texts create genuine issues of fact is "an important question of federal law which has not been, but should be, settled by the Court or has [been] decided ... in a way which is in conflict with applicable decisions of this Court." (*id.*)

B. *Block's Reasons for Granting the Writ Are Based on Misstatements of the Facts and Decisions Below*

A close examination of Block's Petition reveals it to be a distorted presentation of the case.

1. There are no "unrebutted admissions" in the record. Thus, the Court of Appeals did not overlook any such "unrebutted admissions" in finding that issues of material fact exist in this case.

Block argues at pp. 17-26 of its Petition that Dr. Hodosh failed to rebut an "admission" made by his German patent agent that "Ya-Tong" means dental hypersensitivity. Block's argument ignores the abundant rebuttal affidavits submitted by Dr. Hodosh on that issue, namely the affidavit of an expert Chinese translator, the affidavit of an expert dentist and dental historian, and the affidavit of an expert physician. (See decision of Court of Appeals at App. 93a-97a).

In the face of such imposing evidence, Block can do no more than offer belated challenges to the qualifications of Dr. Hodosh's expert translator and belittle the testimony of Dr. Hodosh's expert dentist and dental historian because he is not a translator while ignoring his expert testimony as a dentist and dental historian. The record amply demonstrates that there is sufficient rebuttal affidavits in the record to create what the Court of Appeals called a "head on factual controversy." (App. at 107a).

Block seems to recognize the adequacy of Dr. Hodosh's evidence and adopts the fall-back argument that the so-called "Ya-Tong" admission is not *unrebutted* but is instead *unrebuttable*. Block never suggested in the District Court that the "admission" is unrebuttable and conceded in the Court of Appeals that it is rebuttable. (App. at 108a). The Court of Appeals held that the "admission" was *rebuttable*. (App. at 108a). Block's last-minute turnabout is without foundation in law and is a desperate attempt to avoid the weight of Dr. Hodosh's evidence by precluding its consideration.

In sum, the translation and interpretation of the term "Ya-Tong" presents genuine issues of material fact and the Court of Appeals properly remanded the case for evaluation at trial of competing expert testimony "under the refining fire of cross-examination". (App. at p. 111a).

2. Neither the District Court, the Court of Appeals nor Dr. Hodosh ever denigrated the Chinese references because they are "ancient".

Block argues that a Writ of Certiorari should be granted because the Court of Appeals failed to "give full consideration to the prior art ... by denigrating such prior art as ancient." Block's argument is a misstatement of the Court of Appeals' decision.

The Court's discussion of the teachings of the references in question (headed "The Chinese References") is found at pp. 84a to 98a of the Appendix. A careful examination of that discussion will fail to disclose a single instance where the Court of Appeals accorded the Chinese references any less weight because of their age. Moreover, Block's Petition cites not one single instance where the Court of Appeals even *hinted* that it gave diminished consideration to the Chinese references because they are ancient. Indeed, there is no indication that the District Court or the Court of Appeals cared one bit how old the references are.[3]

This is consistent with the position taken by Dr. Hodosh in his brief before the Court of Appeals at page 41:

> It is not the position of Dr. Hodosh and RVI that the Chinese references should be dismissed simply because they are old. Rather, the ancient references should be

[3] The Court of Appeals did, on occasion, characterize the Chinese references as "ancient". This was appropriate since the references are indeed quite old. For example, *Ben Cao Gang Mu* states on its face that it was "Written by: Li-Shi-Zhen in Ming Dynasty" (*i.e.*, during the period 1368 to 1644 A.D.). (App. at page 90a). These ancient references did not become young again when they were passed through a printing press and republished in 1963 and 1965.

> dismissed because they are incredible and a person of ordinary skill in the art would pay no attention to them.

Dr. Hodosh restated this position in his reply brief at page 21:

> Nor ... [has Dr. Hodosh] argued that these references are not available as prior art because they are old. The issue here is credibility, not age.

Block is the only one who ever raised the "age" of the Chinese references as an issue in this case. Apparently, Block believes that this bogus issue is useful as a red herring to distract this Court from the weakness of Block's position.

CONCLUSION

In view of the foregoing, it is respectfully submitted that the Writ should not be granted.

Respectfully submitted

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